

**WARNING: THROMBOTIC MICROANGIOPATHY and THROMBOEMBOLISM**

Cases of thrombotic microangiopathy and thrombotic events were reported when on average a cumulative amount of >100 U/kg/24 hours of activated prothrombin complex concentrate was administered for 24 hours or more to patients receiving Hemlibra prophylaxis. Monitor for the development of thrombotic microangiopathy and thrombotic events if activated prothrombin complex concentrate (aPCC) is administered. Discontinue aPCC and suspend dosing of Hemlibra if symptoms occur.

**SCHEDULING STATUS****S4****1 NAME OF THE MEDICINE**

Hemlibra® 30 mg/1 mL solution for injection

Hemlibra® 60 mg/0,4 mL solution for injection

Hemlibra® 105 mg/0,7 mL solution for injection

Hemlibra® 150 mg/1 mL solution for injection

Sugar free.

**2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Hemlibra contains emicizumab as the active substance.

**Hemlibra 30 mg/1 mL solution for injection:** Each vial of 1 mL contains 30 mg of emicizumab at a concentration of 30 mg/mL.

**Hemlibra 60 mg/0,4 mL solution for injection:** Each vial of 0,4 mL contains 60 mg of emicizumab at a concentration of 150 mg/mL.

**Hemlibra 105 mg/0,7 mL solution for injection:** Each vial of 0,7 mL contains 105 mg of emicizumab at a concentration of 150 mg/mL.



**Hemlibra 150 mg/1 mL solution for injection:** Each vial of 1 mL contains 150 mg of emicizumab at a concentration of 150 mg/mL.

For the full list of excipients, see section 6.1.

Hemlibra is a humanised monoclonal modified immunoglobulin G4 (IgG4) antibody produced using recombinant DNA technology in mammalian Chinese Hamster Ovary (CHO) cells.

### **3 PHARMACEUTICAL FORM**

Hemlibra is a colourless to slightly yellow solution.

Hemlibra solution for injection vials are for single-use only.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic Indications**

Hemlibra is indicated for routine prophylaxis to prevent bleeding or reduce the frequency of bleeding episodes in adults and children with haemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors.

There are limited data in infants less than 1 year of age.

#### **4.2 Posology and method of administration**

##### **General**

Treatment should be initiated under the supervision of a medical practitioner experienced in the treatment of haemophilia and/or bleeding disorders.

##### **Posology**

Treatment with bypassing agents should be discontinued 24 hours before starting Hemlibra therapy (see section 4.4). Factor VIII (FVIII) prophylaxis may be continued for the first 7 days of Hemlibra treatment.

##### **Recommended dosage (all patients)**

The recommended loading dose is 3 mg/kg administered as a subcutaneous injection once weekly for the first 4 weeks, followed by a maintenance dose from week 5 of either:

- 1,5 mg/kg once weekly, or
- 3 mg/kg every two weeks, or
- 6 mg/kg every four weeks

The maintenance dose regimen should be selected based on the medical practitioner and patient/caregiver dosing regimen preference to support adherence.

### **Method of administration**

Hemlibra solution is a sterile, preservative-free, and ready to use solution for subcutaneous injection that does not need to be diluted.

Hemlibra solution should be inspected visually to ensure there is no particulate matter or discolouration prior to administration.

**Hemlibra is for subcutaneous use only.** Hemlibra should be administered using appropriate aseptic technique (see section 6.6).

The injection should be restricted to the recommended injection sites: the abdomen, the upper outer arms and the thighs (see section 5.1). No data are available on injection at other sites of the body.

Administration of Hemlibra subcutaneous injection in the upper outer arm should be performed by a trained caregiver or healthcare professional.

Alternating the site of injection may help prevent or reduce injection site reactions (see section 4.8). Hemlibra subcutaneous injection should not be administered into areas where the skin is red, bruised, tender or hard, or areas where there are moles or scars.

During treatment with Hemlibra, other medicinal products for subcutaneous administration should, preferably, be injected at different anatomical sites.

A 1 mL syringe should be used for an injection up to 1 mL of Hemlibra solution. Administer doses of Hemlibra greater than 1 mL and up to 2 mL with a 2 mL or 3 mL syringe.

Recommended criteria for syringes, needles and vial adaptor are defined to ensure correct and safe administration of Hemlibra. These criteria are based on handling considerations (e.g. dosing accuracy, subcutaneous injection), Hemlibra characteristics (e.g. viscosity), and compatibility between Hemlibra and device materials.



*Administration by the patient and/or caregiver:*

Hemlibra is intended for use under the guidance of a healthcare professional. After proper training in subcutaneous injection technique, a patient may self-inject Hemlibra, or the patient's caregiver may administer Hemlibra, if their medical practitioner determines that it is appropriate, see Patient Instructions for Use below.

The medical practitioner and the caregiver should determine the appropriateness of the child self-injecting Hemlibra. However, self-administration is not recommended for children below 7 years of age.

**Duration of treatment**

Hemlibra is intended for long-term prophylactic treatment.

**Dosage adjustments during treatment**

No dosage adjustments of Hemlibra are recommended.

**Delayed or missed doses**

If a patient misses a scheduled weekly subcutaneous injection of Hemlibra, the patient should be instructed to take the missed dose as soon as possible, approximately 24 hours before the next scheduled dose. The patient should then administer the next dose on the usual scheduled dosing day. The patient should not take two doses on the same day to make up for a missed dose.

**Patient: Instructions for Use.**

**Hemlibra Injection - Single-Dose Vial(s)**

**Using either the TRANSFER NEEDLE WITH FILTER, TRANSFER NEEDLE or VIAL**

**ADAPTOR option**

You must read, understand and follow the Instructions for Use before injecting Hemlibra. Your healthcare professional should show you how to prepare, measure, and inject Hemlibra properly before you use it for the first time. Ask your healthcare professional if you have any questions.



### Important Information:

- **Do not** inject yourself or someone else unless you have been shown how to by your healthcare professional.
- Make sure the name Hemlibra appears on the box and vial label.
- Before opening the vial, read the vial label to make sure you have the correct medicine strength(s) needed to give the dose prescribed by your healthcare professional. Depending on your dose, you may need to use more than 1 vial to give yourself the correct dose.
- Check the expiry date on the box and vial label. **Do not** use if the expiry date has passed.
- **Only use the vial once.** After you inject your dose, dispose of (throw away) any unused Hemlibra left in the vial. Do not save unused medicine in the vial for later use.
- **Only use the syringes, transfer needles with filter or transfer needles or vial adaptors, and injection needles that your healthcare professional prescribes.**
- **Use the syringes, transfer needles with filter or transfer needles or vial adaptors and injection needles only once. Dispose of (throw away) any used caps, vials, syringes and needles.**
- If your prescribed dose is more than 2 mL, you will need to have more than one subcutaneous injection of Hemlibra; contact your healthcare professional for the appropriate injection instructions.

You must inject Hemlibra only under the skin.

### Storing Hemlibra vials, needles, vial adaptors and syringes:

- Keep the vial in the original box to protect the medicine from light.
- Keep the vials, vial adaptors, needles and syringes out of the sight and reach of children.  
Store the vial in the refrigerator.
- **Do not** freeze.
- **Do not** shake the vial.
- Take the vial out of the refrigerator 15 minutes before use and allow it to reach room temperature before preparing an injection.

- Once removed from the refrigerator, the unopened vial can be kept at room temperature (below 30 °C) for up to 7 days. After storage at room temperature unopened vials may be returned to the refrigerator. The total amount of time outside of the refrigerator and at room temperature should not exceed 7 days.
- Discard vials that have been kept at room temperature for more than 7 days or have been in temperatures above 30 °C.

Keep the transfer needle with filter or transfer needle or vial adaptor, injection needle and syringe dry.

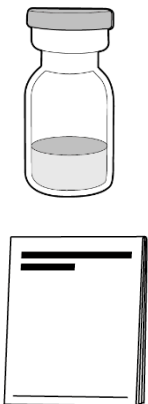
### Inspecting the medicine and your supplies

- Collect all supplies listed below to prepare and give your injection.
- Check the expiry date on the box, on the vial label and on the supplies listed below. Do not use if the expiry date has passed.

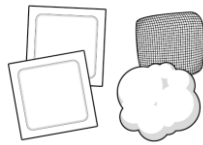
### Do not use the vial if:

- the medicine is cloudy, hazy or coloured.
- the medicine contains particles.
- the cap covering the stopper is missing.
- Inspect the supplies for damage. Do not use if they appear damaged or if they have been dropped.
- Place the supplies on a clean, well-lit flat work surface.

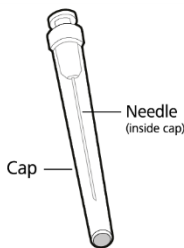
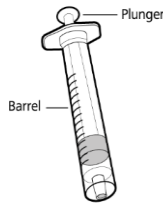
### INCLUDED IN THE BOX:

	<ul style="list-style-type: none"><li>• Vial containing the medicine</li><li>• Hemlibra instructions for Use</li></ul>
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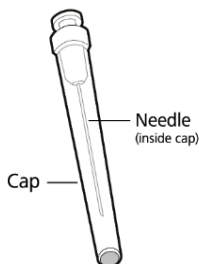
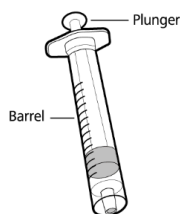
### NOT INCLUDED IN THE BOX:



**EITHER**



**OR**



- **Alcohol wipes**

**Note:** If you need to use more than 1 vial to inject your prescribed dose, you must use a new alcohol wipe for each vial.

- **Gauze**
- **Cotton Ball**
- **Syringe (For use with transfer needle with filter)**

**Note:** For injection amount up to 1 mL use a **1 mL syringe**.

For injection amount between 1mL and 2 mL use a **2 mL or 3 mL syringe**.

- **18G Transfer needle with 5 micrometre filter**

**Note:** If you need to use more than 1 vial to inject your prescribed dose, you must use a new transfer needle with filter for each vial.

**Do not** use the transfer needle with filter to inject the medicine.

- **Syringe (For use with transfer needle)**

**Note:** For injection amount up to 1 mL use a 1 mL syringe.

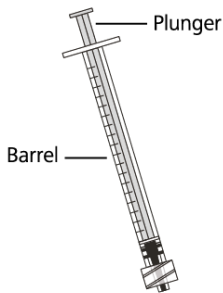
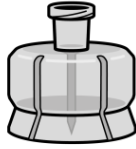
For injection amount between 1mL and 2 mL use a 2 or 3 mL syringe.

- **18G Transfer Needle**

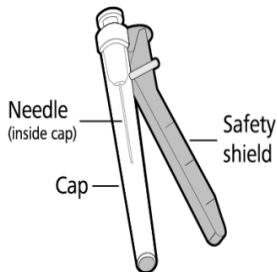
**Note:** If you need to use more than 1 vial to inject your prescribed dose, you must use a new transfer needle for each vial.

Do not use the transfer needle to inject medicine.

**OR**



**FOR ALL OPTIONS**



- **Vial adaptor** (To be added on top of vial).

**Note:** Used for withdrawing medicine from the vial to the syringe. If you need to use more than 1 vial to inject your prescribed dose, you must use a new vial adaptor for each vial.



**Do not insert injection needle into vial adaptor.**

- **Syringe with Low Dead Space (LDS) Plunger**

**Important:**

- For injection amount up to 1 mL use a **1 mL LDS syringe**.
- For injection amount over 1 mL use **3 mL LDS syringe**.

**Note:** Do not use 3 mL LDS syringe for doses up to 1 mL.

- **Injection Needle with safety shield** (Used to inject medicine)

**Transfer needle with filter and transfer needle: Do not use the injection needle to withdraw medicine from vial.**

**Vial adaptor:** Do not insert the injection needle into the vial adaptor or use the injection needle to withdraw medicine from the vial.

Sharps disposal container



### Get Ready:

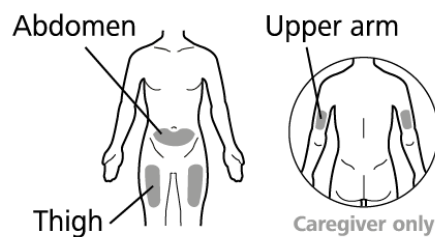
- Before use, allow the vial(s) to warm up to room temperature for about 15 minutes on a clean flat surface away from direct sunlight.
- Do not try to warm the vial by any other way.
- **Wash your hands** well with soap and water.

Figure A



### Selecting and preparing an injection site:

- Clean the chosen injection site area using an alcohol wipe.
- Let the skin dry for about 10 seconds. Do not touch, fan or blow on the cleaned area before your injection.



### For your injection you can use your:

- Thigh (front and middle).
- Stomach area (abdomen), except for 5 cm around the navel (belly button).
- Outer area of the upper arm (only if a caregiver is giving the injection).
- You should use a different injection site each time you give an injection, at least 2,5 cm away from the area you used for your previous injection.
- Do not inject into areas that could be irritated by a belt or waistband. Do not inject into moles, scars, bruises, or areas where the skin is tender, red, hard or the skin is broken.

### Preparing the syringe for the injection

- Do not touch exposed needles or place them on a surface once the cap has been removed.
- Once the syringe has been filled with the medicine, it must be used immediately.



- Once the injection needle cap has been removed, the medicine in the syringe must be injected under the skin within 5 minutes. Do not use the syringe if the needle touches any surface.

### **Important information after the injection**

- Do not rub the injection site after an injection.
- If you see drops of blood at the injection site, you can press a sterile cotton ball or gauze over the injection site for at least 10 seconds, until bleeding has stopped.

If you have bruising (small area of bleeding under the skin), an ice pack can also be applied with gentle pressure to the site. If bleeding does not stop, please contact your healthcare professional.

### **Disposing of the medicine and supplies:**

**Important: Always keep the sharps disposal container out of reach of children.**

- Throw away any used vial(s), needles or vial adaptors, vial/injection needle caps and used syringes in a sharps or puncture-proof container.
- Put your used needles or vial adaptors and syringes in a sharps disposal container straight away after use. Do not dispose of (throw away) any loose needles and syringes in your household waste.
- If you do not have a sharps disposal container, you may use a household container that is:
  - made of heavy-duty plastic.
  - can be closed with a tight-fitting, puncture resistant lid, without sharps being able to come out.
  - upright and stable during use.
  - leak-resistant.
  - properly labelled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your local guidelines for the right way to dispose of (throw away) your sharps disposal container.

**Do not dispose of (throw away) any used sharps disposal container in your household waste unless your local guidelines permit this. Do not recycle your used sharps disposal container.**

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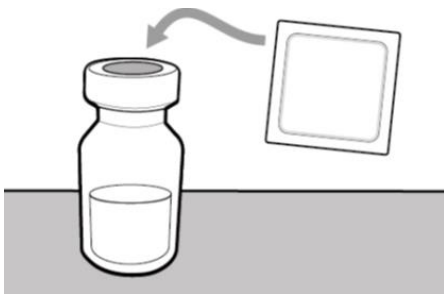
## 1. PREPARATION FOR USE USING THE TRANSFER NEEDLE WITH FILTER OPTION

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### Step 1. Remove vial cap and clean top



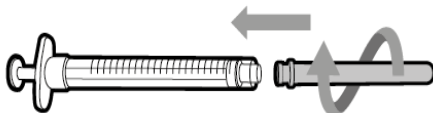
- Take the cap off the vial(s).
- Throw away the vial cap(s) into the sharps disposal container.



- Clean the top of the vial(s) stopper with an alcohol wipe.

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### Step 2. Attach transfer needle with filter to syringe

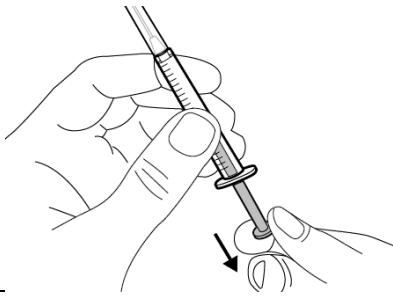


Push and twist

- **Push and twist the transfer needle with filter clockwise** on to the syringe until it is fully attached.
- Slowly pull back on the plunger and draw air into the syringe that is the

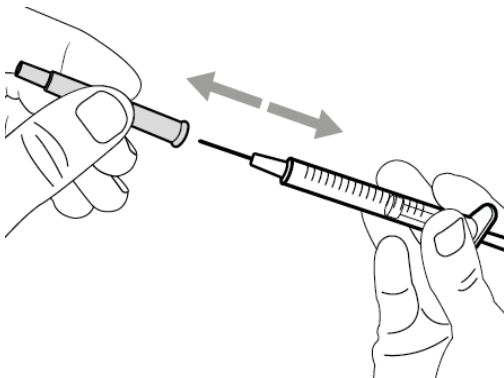
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same amount as your prescribed dose.



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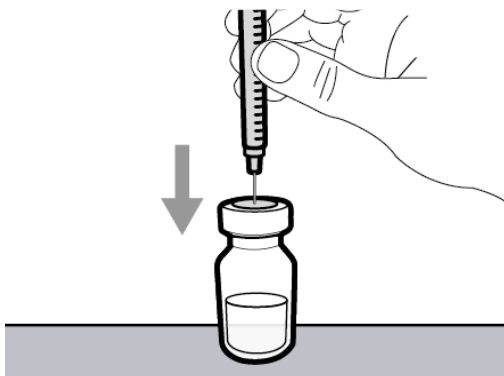
**Step 3. Uncap transfer needle with filter**



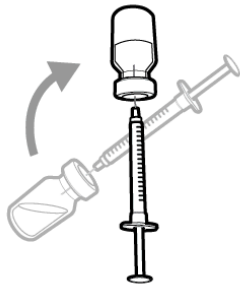
- Hold the syringe by the barrel with the transfer needle with filter pointing up.
- Carefully pull the transfer needle with filter cap straight off and away from your body. **Do not throw the cap away. Place the transfer needle with filter cap down on a clean flat surface.** You will need to recap the transfer needle with filter after transferring the medicine.
- **Do not touch** the needle tip or place it on a surface after the needle cap has been removed.

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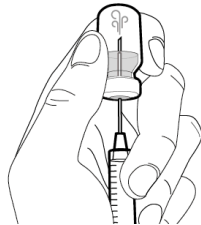
**Step 4. Inject air into vial**



- Keep the vial on the flat working surface and insert the transfer needle with filter and syringe straight down into the centre of the vial stopper.

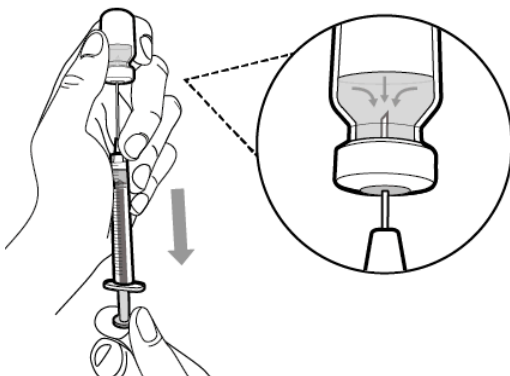


- Keep the needle in the vial and turn the vial upside down.



- With the needle pointing upwards, push on the plunger to inject the air from the syringe **above the medicine.**
- Keep your finger pressed down on the syringe plunger.
- **Do not** inject air into the medicine as this could create air bubbles or foam in the medicine.

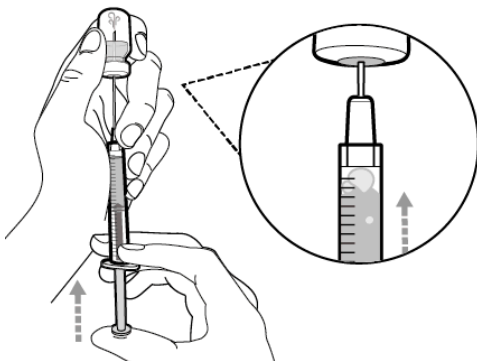
### Step 5. Transfer medicine to syringe



- Slide the tip of the needle down so that it is **within the medicine.**
- Slowly pull back the plunger to prevent air bubbles/foam.  
Fill the syringe with more than the amount of medicine needed for your prescribed dose.
- Be careful not to pull the plunger out of the syringe.

**Important:** If your prescribed dose is more than the amount of medicine in the vial, **withdraw all of the medicine** and go to the “**Combining Vials**” section now.

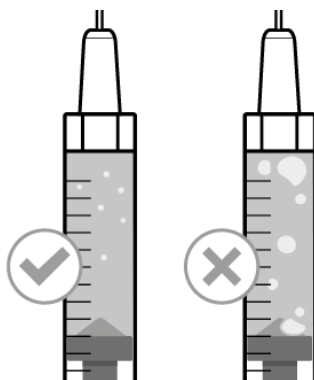
### Step 6. Remove air bubbles



- Keep the needle in the vial and check the syringe for larger air bubbles.

Large air bubble can reduce the dose you receive.

- **Remove the larger air bubbles** by gently **tapping** the syringe barrel with your fingers until the air bubbles rise to the top of the syringe. Move the tip of the needle **above the medicine** and slowly push the plunger up to push the air bubbles out of the syringe.



- If the amount of medicine in the syringe is now at or below your prescribed dose, move the tip of the needle to **within the medicine** and slowly **pull** back the plunger until you have **more** than the amount of medicine needed for your **prescribed dose**.

- Be careful not to pull the plunger out of



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the syringe.

- Repeat the steps above until you have removed the larger air bubbles.

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**Note:** Ensure you have enough medicine in the syringe to complete your dose before moving onto the next step. If you cannot remove all medicine, turn the vial upright to reach the remaining amount.

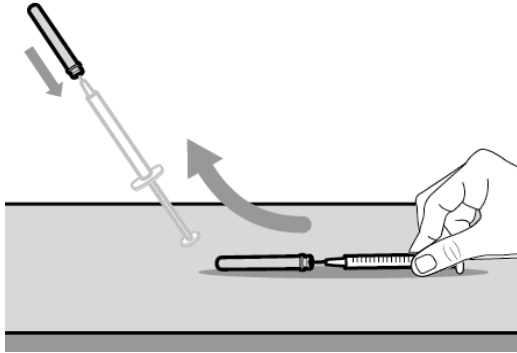


**Do not** use the transfer needle with filter to inject medicine as this may cause pain and bleeding.

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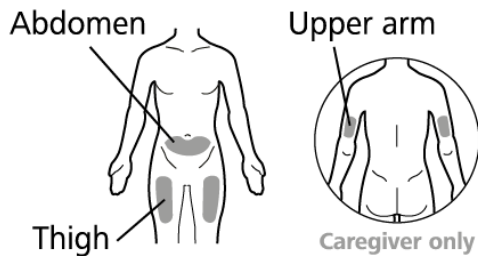
## 2. INJECTION

### Step 7. Recap transfer needle with filter



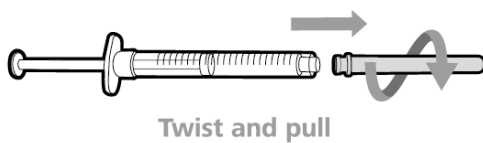
- Remove the syringe and transfer needle with filter from the vial.
- **Using one hand, slide** the transfer needle with filter into the cap and **scoop upwards** to cover the needle.
- Once the needle is covered, push the transfer needle with filter cap towards the syringe to fully attach it with **one hand** to prevent accidentally injuring yourself with the needle.

### Step 8. Clean injection site



- Select and **clean** your injection site with an alcohol wipe.

### Step 9. Remove transfer needle

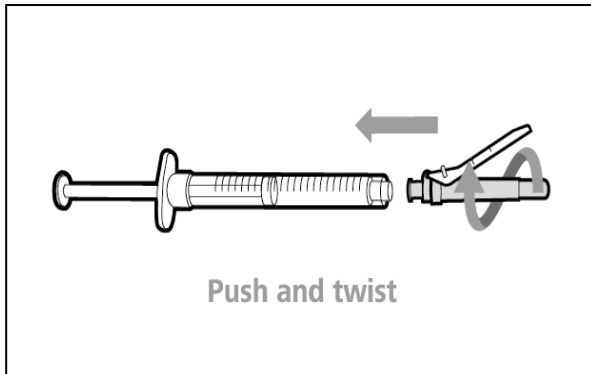


- Remove the transfer needle with filter from the syringe by twisting anticlockwise and gently pulling.
- Throw away the used transfer needle with filter into a sharps disposal container.



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### Step 10. Attach injection needle to syringe



- Push and twist the injection needle clockwise onto the syringe until it is fully attached.

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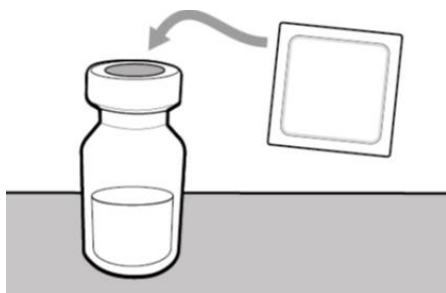
## 1. PREPARATION FOR USE USING THE TRANSFER NEEDLE OPTION

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### Step 1. Remove vial cap and clean top



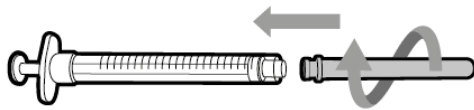
- Take the cap off the vial(s).



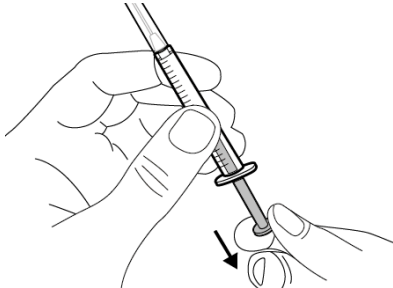
- Clean the top of the vial(s) stopper with an alcohol wipe.
- Dispose of (throw away) the vial cap(s) into the sharps disposal container.

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**Step 2. Attach transfer needle to syringe**



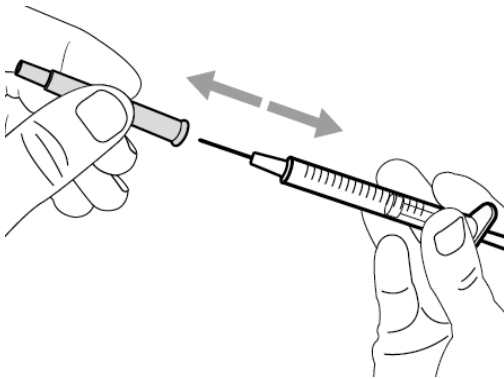
Push and twist



- **Push and twist the transfer needle clockwise** on to the syringe until it is fully attached.
- Slowly pull back on the plunger and draw air into the syringe that is the same amount for your prescribed dose.

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**Step 3. Uncap transfer needle**



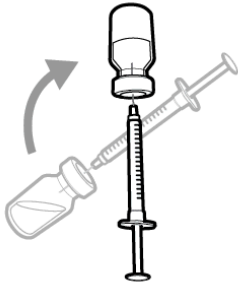
- Hold the syringe by the barrel with the transfer needle pointing up.
- Carefully pull the transfer needle cap straight off and away from your body. **Do not throw the cap away. Place the transfer needle cap down on a flat surface.** You will need to recap the transfer needle after transferring the medicine.
- **Do not touch** the needle tip or place it on a surface after the needle cap has been removed.

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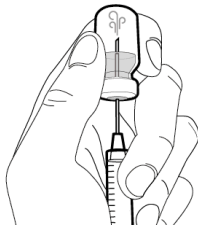
**Step 4. Inject air into vial**



- Keep the vial on the flat working surface and insert the transfer needle and syringe straight down into the centre of the vial stopper.

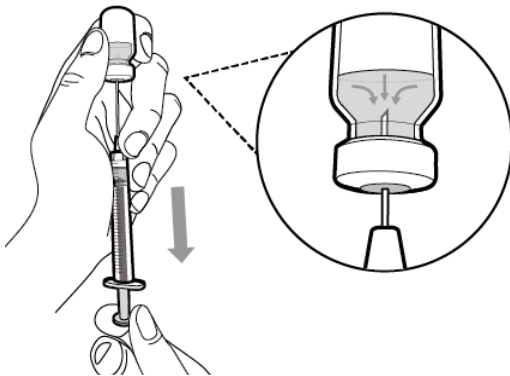


- Keep the needle in the vial and turn the vial upside down.



- With the needle pointing upwards, push on the plunger to inject the air from the syringe **above the medicine**.
- Keep your finger pressed down on the syringe plunger.
- **Do not** inject air into the medicine as this could create air bubbles in the medicine.

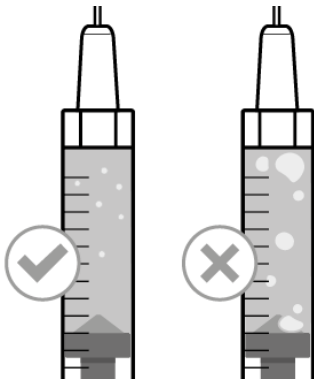
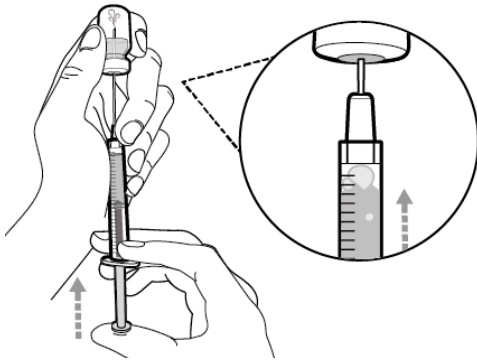
#### Step 5. Transfer medicine to syringe



- Slide the tip of the needle down so that it is within the medicine.
- Slowly pull back the plunger to fill the syringe with more than the amount of medicine needed for your prescribed dose.
- Be careful not to pull the plunger out of the syringe.

**Important:** If your prescribed dose is more than the amount of medicine in the vial, **withdraw all of the medicine** and go to the **Combining Vials** section now.

### Step 6. Remove air bubbles



- Keep the needle in the vial and check the syringe for larger air bubbles. Too large an air bubble can reduce the dose you receive.
- **Remove the larger air bubbles** by gently tapping the syringe barrel with your fingers until the air bubbles rise to the top of the syringe. Move the tip of the needle **above the medicine** and slowly push the plunger up to push the air bubbles out of the syringe
- If the amount of medicine in the syringe is now at or below your prescribed dose, move the tip of the needle to **within the medicine** and slowly **pull** back the plunger until you have **more** than the amount of medicine needed for your **prescribed dose**.
- Be careful not to pull the plunger out of the syringe
- Repeat the steps above until you have removed the larger air bubbles.

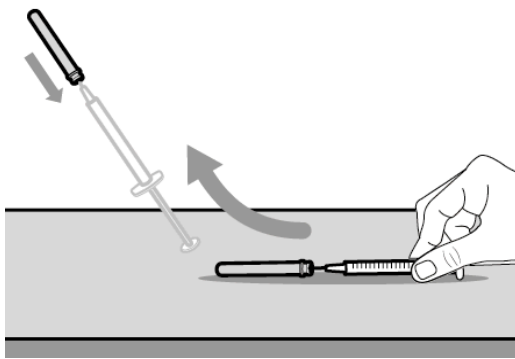
**Note:** Ensure you have enough medicine in the syringe to complete your dose before moving onto the next step. If you cannot remove all of the medicine, turn the vial upright to reach the remaining amount.



**Do not** use the transfer needle to inject medicine as this may cause harm such as pain and bleeding.

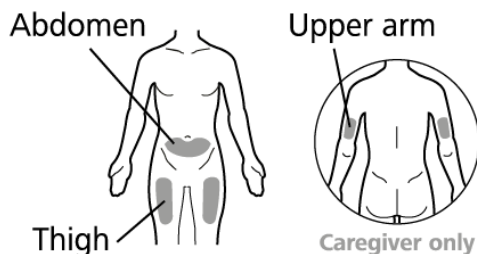
## 2. INJECTION

### Step 7. Recap transfer needle



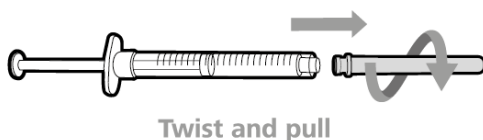
1. Remove the syringe and transfer needle from the vial.
2. **Using one hand, slide** the transfer needle into the cap and **scoop upwards** to cover the needle.
3. Once the needle is covered, push the transfer needle cap towards the syringe to fully attach it with **one hand** to prevent accidentally hurting yourself with the needle

### Step 8. Clean injection site



- Select and clean your injection site with an alcohol wipe.

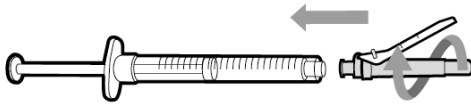
### Step 9. Remove transfer needle



- Remove the transfer needle from the syringe by twisting anticlockwise and gently pulling.
- Dispose of (throw away) the used transfer needle into a sharps disposal container.

**Step 10. Attach injection needle to syringe**

- Push and twist the injection needle clockwise onto the syringe until it is fully attached.



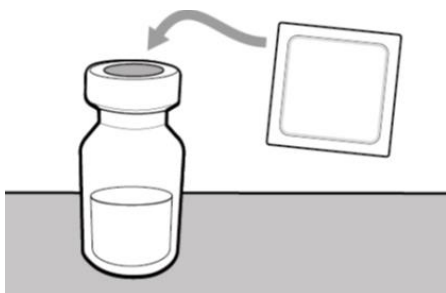
Push and twist

**PREPARATION FOR USE USING THE VIAL ADAPTOR OPTION**

**Step 1. Remove vial cap and clean top**



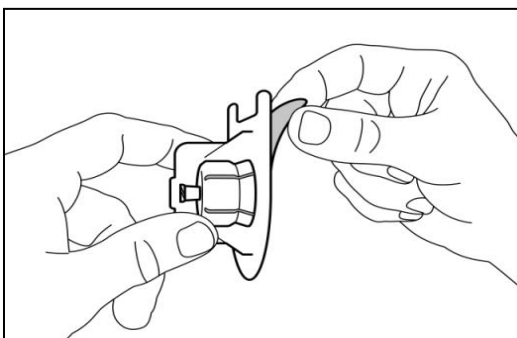
- Take the cap off the vial(s).
- Throw away the vial cap(s) into the sharps disposal container.



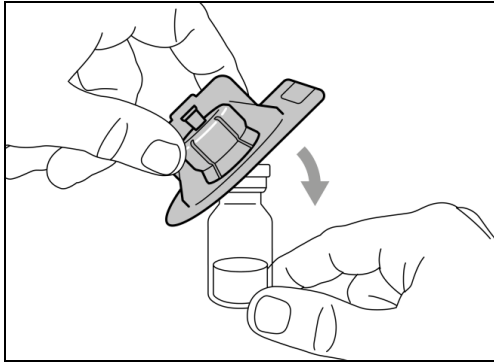
- Clean the top of the vial(s) stopper with an alcohol wipe.

**Step 2. Insert vial adaptor onto vial**

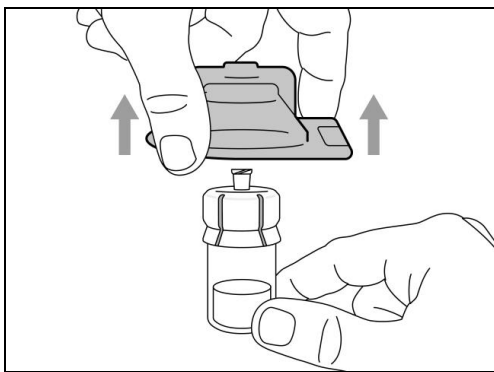
- Peel off back to open the blister pack.



- ⚠ **Do not remove the vial adaptor from the clear plastic blister pack.**

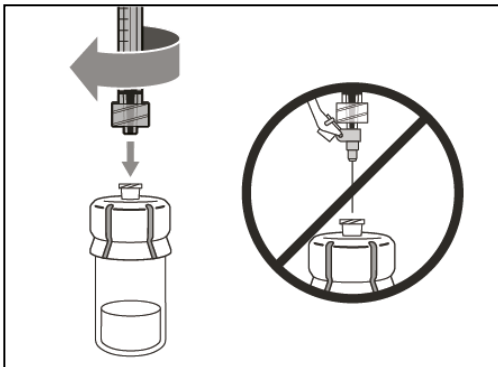


- Firmly press down the plastic blister pack with the vial adaptor onto the new vial at an angle, until you hear a “click”.



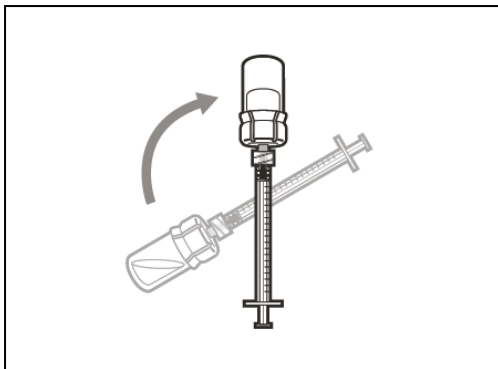
- Remove and throw away the plastic blister pack.
- **Do not** touch the tip of vial adaptor.

### Step 3. Connect syringe to vial adaptor



- **Remove syringe cap** (if required).
- **Push and twist the syringe clockwise** on to the vial adaptor until it is fully attached.

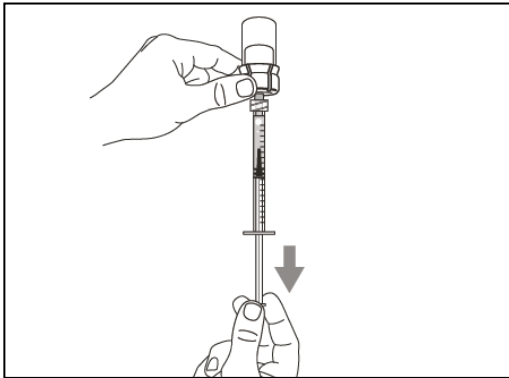
### Step 4. Transfer medicine to syringe



- Keep the vial adaptor attached to the syringe and turn the vial upside down.

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### Step 5



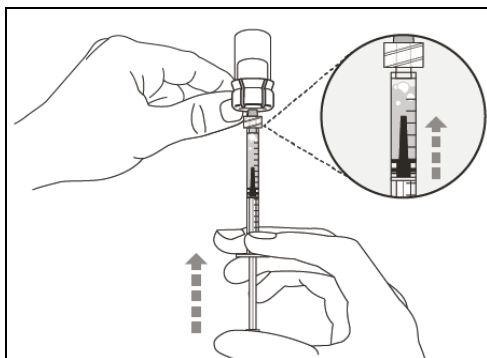
- With the syringe pointing upwards, slowly pull back the plunger to **fill the syringe with** more than the amount of **medicine** needed for your prescribed dose.
- **Hold plunger firmly** to ensure it does not pull back in.
- Be careful not to pull the plunger out of the syringe.

---

**Important:** If your prescribed dose is more than the amount of Hemlibra in the vial, **withdraw all medicine** and go to the **“Combining Vials”** section now

---

### Step 6. Remove air bubbles



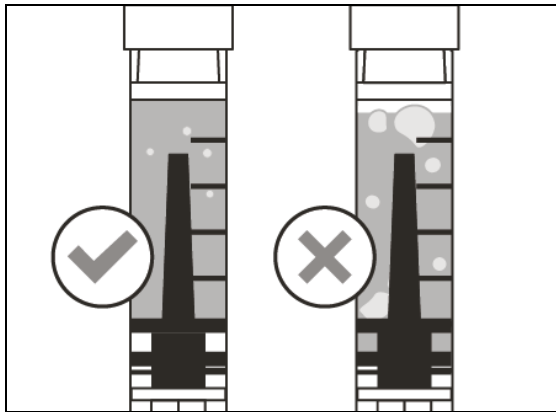
- Keep the vial attached to the syringe and **check the syringe for larger air bubbles**. Large air bubbles can reduce the dose you receive.

---

### Step 7

- **Remove the larger air bubbles** by gently **tapping** the syringe barrel with your finger until the air bubbles rise to the top of the syringe. **Slowly push the plunger** to push the large air bubbles out of the syringe.
-



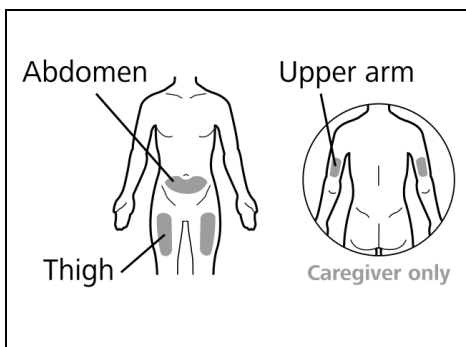


- If the amount of medicine in the syringe is now at or below your prescribed dose, slowly pull back the plunger until you have **more** than the amount of medicine needed for your **prescribed dose**.
- Be careful not to pull the plunger out of the syringe.
- Repeat the steps above until you have removed the large air bubbles.

**Note:** Ensure you have enough medicine in the syringe to complete your dose before moving on to the next step.

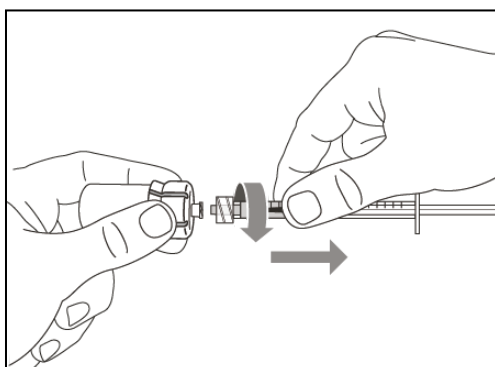
## 2. INJECTION

### Step 8. Clean injection site



- Select and **clean** your injection site with an alcohol wipe.

### Step 9. Remove syringe from vial adaptor

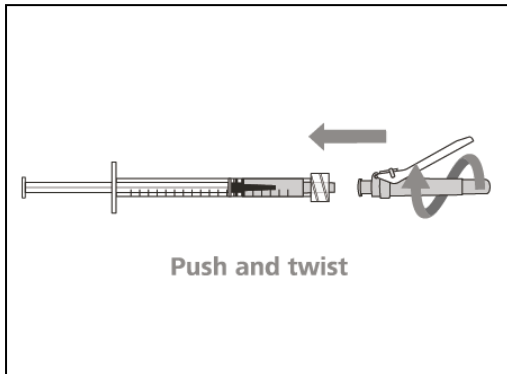


- Remove the syringe from the vial adaptor by twisting anticlockwise and gently pulling.
- Throw away the used vial/vial adaptor into a sharps disposal container.

---

**Step 10. Attach injection needle to syringe**

- Push and twist the injection needle clockwise onto the syringe until it is fully attached.
- **Do not** insert the injection needle into vial adaptor or use the injection needle to withdraw medicine from vial.

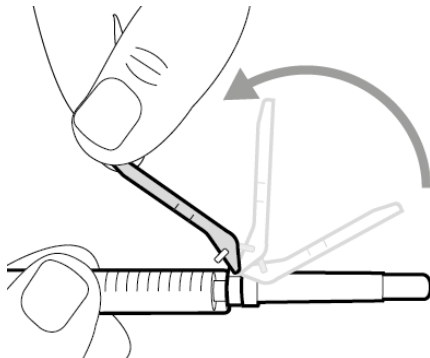


Follow the instructions below for [both] the **TRANSFER NEEDLE WITH FILTER**, **TRANSFER NEEDLE** and **VIAL ADAPTOR** options

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**Step 11. Move safety shield**

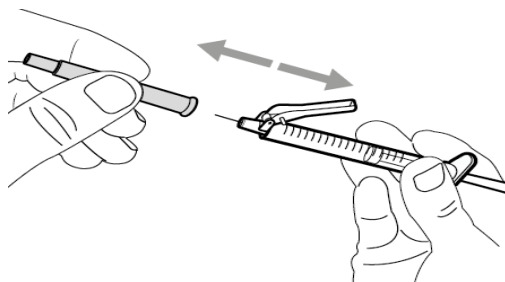
- Move the safety shield away from the needle and **towards** the syringe barrel.



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**Step 12. Uncap injection needle**

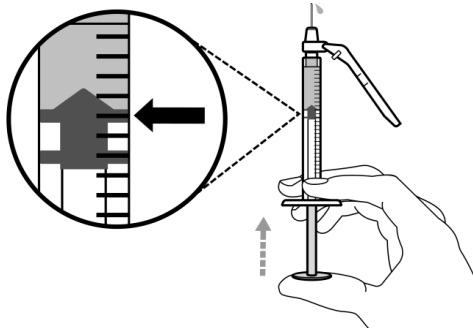
- Carefully pull the injection needle cap **straight away** from the syringe.
- Dispose of (throw away) the cap into a sharps disposal container
- **Do not touch** the needle tip or allow it to touch any surface.
- After the injection needle cap has been removed, the medicine in the syringe must be injected within 5 minutes.



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### Step 13. Adjust plunger to prescribed

dose

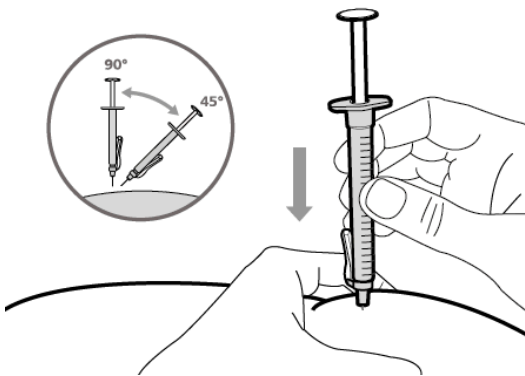


- Hold the syringe with the needle pointing up and slowly push the plunger to your prescribed dose.
- **Check your dose**, ensure the top rim of the plunger is in line with the mark on the syringe for your prescribed dose.

---

### Step 14. Subcutaneous (under the skin)

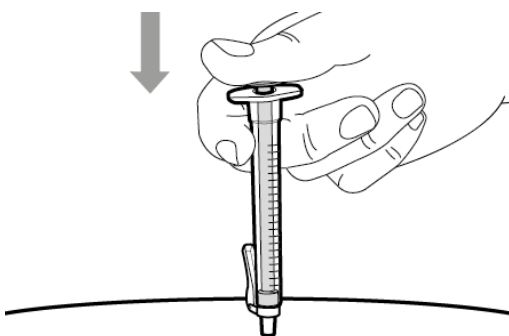
Injection



- Pinch the selected injection site and fully insert the needle at a **45° to 90° angle** with a quick, firm action. **Do not** hold or push on the plunger while inserting the needle.
- Hold the position of the syringe and let go of the pinched injection site.

---

### Step 15. Inject the medicine



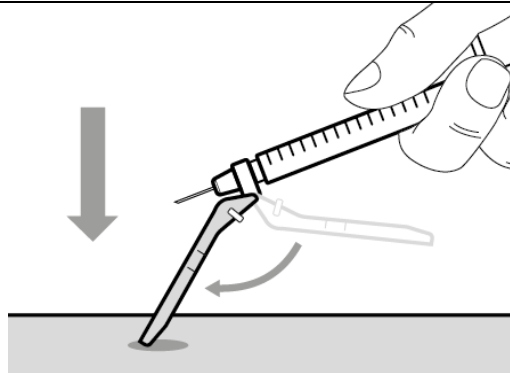
- Slowly inject all of the medicine by gently pushing the plunger all the way down.
- Remove the needle and syringe from the injection site at the same angle as inserted.

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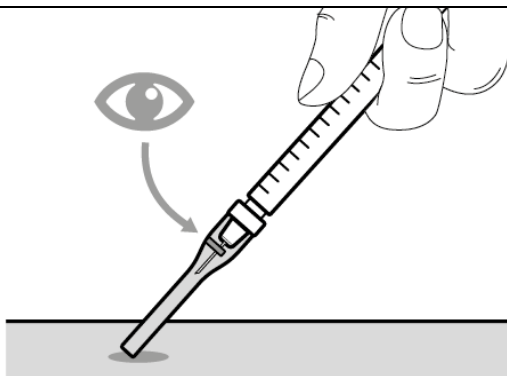
## 3. DISPOSAL

### Step 16. Cover needle with safety shield

- Move the safety shield forward 90°, away from the syringe barrel.
- Holding the syringe with one hand,

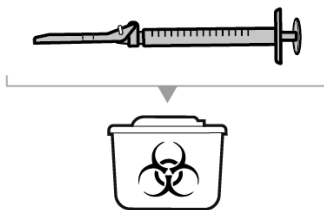


**press the safety shield down** against a flat surface with a firm, quick motion until you hear a “click”.



- If you do not hear a click, look to see that the needle is fully covered by the safety shield.
- Keep your fingers behind the safety shield and away from the needle at all times.
- **Do not** detach injection needle

**Step 17. Dispose of (throw away) the syringe and needle.**



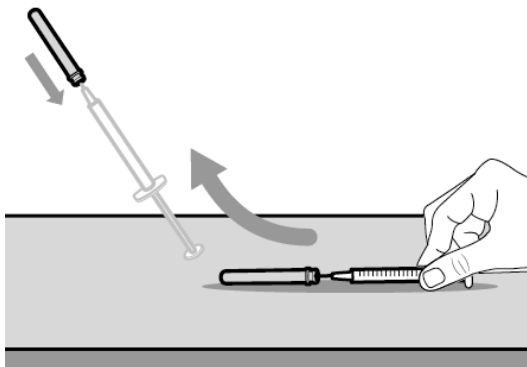
- Put your used needles and syringes in a sharps disposal container right away after use. For further information refer to the section “Disposing of the medicine and supplies”.
- **Do not** try to remove the used injection needle from the used syringe.
- **Do not recap** the injection needle with the cap.
- **Important:** Always keep the sharps disposal container out of reach of children.
- Throw away any used caps, vial(s), needles or adaptors and syringes in a sharps or puncture-proof container.

### Combining Vials using the TRANSFER NEEDLE WITH FILTER option

If you need to use more than 1 vial to get to your total prescribed dose, follow these steps after you have drawn up the medicine from the first vial:

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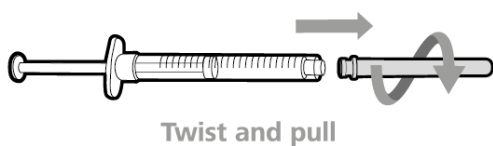
#### Step A. Recap transfer needle with filter



- Remove the syringe and transfer needle with filter from the first vial.
- **Using one hand**, slide the transfer needle with filter into the cap and **scoop upwards** to cover the needle.
- Once the needle is covered, push the transfer needle with filter cap toward the syringe to fully attach it with **one hand** to prevent accidentally injuring yourself with the needle.

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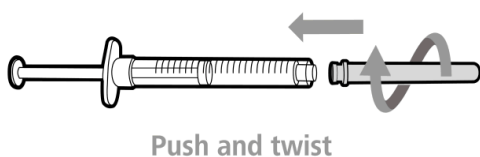
#### Step B. Remove transfer needle with filter



- Remove the transfer needle with filter from the syringe by twisting anticlockwise and gently pulling.
- Throw away the used transfer needle with filter into a sharps disposal container.

---

#### Step C. Attach a new transfer needle with filter to syringe



**Note: You must use a new transfer needle with filter each time you withdraw medicine from a new vial.**

- Push and twist a **new** transfer needle with filter clockwise on to the syringe until it is fully attached.
- Slowly pull back the plunger and draw

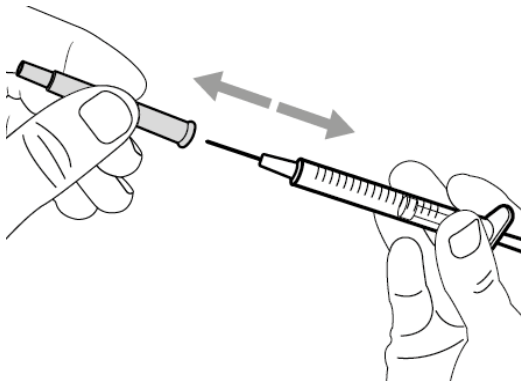
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some air into the syringe.

---

**Step D. Uncap transfer needle with**

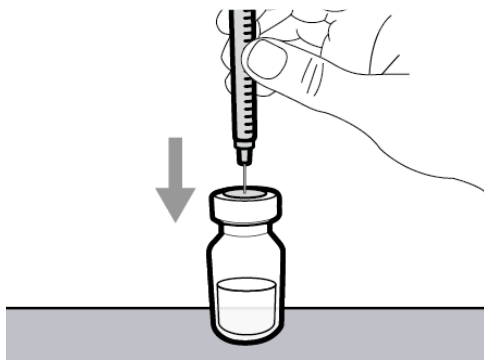
**filter**



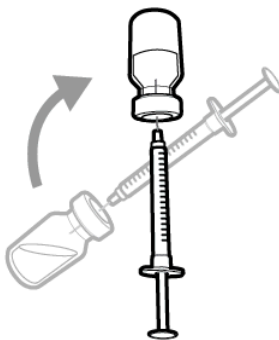
- Hold the syringe by the barrel with the transfer needle with filter cap pointing up.
- Carefully pull the transfer needle with filter cap straight off and away from your body. **Do not throw** the cap away. You will need to recap the transfer needle with filter after drawing up the medicine.
- **Do not touch** the needle tip.

---

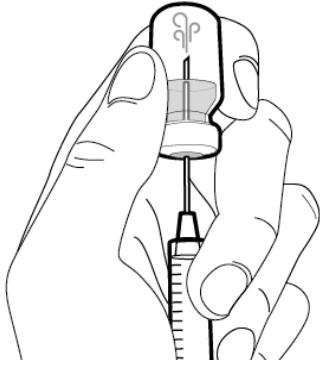
**Step E. Inject air into vial**



- With the new vial on the flat working surface, insert the new transfer needle with filter and syringe, straight down into the **centre** of the vial stopper.

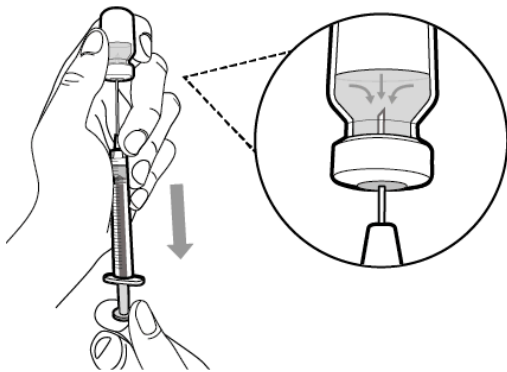


- Keep the transfer needle with filter in the vial and turn the vial upside down.



- With the needle pointing upwards, inject the air from the syringe **above the medicine**.
- Keep your finger pressed down on the syringe plunger.
- **Do not** inject air into the medicine as this could create air bubbles or foam in the medicine.

#### Step F. Transfer medicine to syringe



- Slide the tip of the needle down so that it is **within the medicine**.
- **Slowly** pull back the plunger to prevent air bubbles/foam. Fill the syringe barrel more than the amount of medicine needed for your prescribed dose.
- Be careful not to pull the plunger out of the syringe.

**Note:** Ensure you have enough medicine in the syringe to complete your dose before moving onto the next steps. If you cannot remove all of the medicine, turn the vial upright to reach the remaining amount.



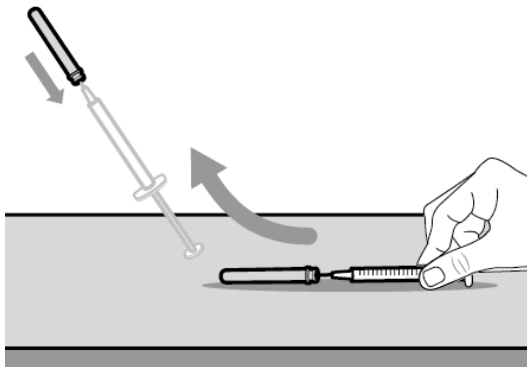
**Do not** use the transfer needle with filter to inject medicine as this may cause harm such as pain and bleeding.

**Repeat steps A to F with each additional vial until you have more than your prescribed dose. Once completed, keep the transfer needle with filter inserted in the vial and return to Step 6. Continue with the remaining steps.**

### Combining Vials using the TRANSFER NEEDLE option

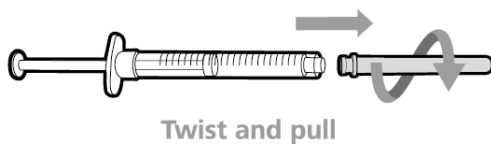
If you need to use more than 1 vial to get to your total prescribed dose, follow these steps after you have drawn up the medicine from the first vial:

#### Step A. Recap transfer needle



- Remove the syringe and transfer needle from the first vial.
- **Using one hand**, slide the transfer needle into the cap and **scoop upwards** to cover the needle.
- Once the needle is covered, push the transfer needle cap toward the syringe to fully attach it with one hand to prevent accidentally injuring yourself with the needle.

#### Step B. Remove transfer needle



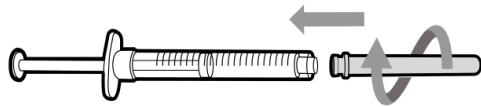
- Remove the transfer needle from the syringe by twisting anticlockwise and gently pulling.
- Dispose of (throw away) the used transfer needle into a sharps disposal container.

#### Step C. Attach a new transfer needle to Syringe

**Note: You must use a new transfer needle each time you withdraw medicine from a new vial.**

- Push and twist a **new** transfer needle





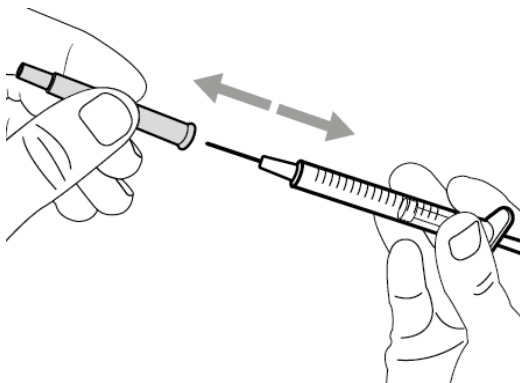
Push and twist

clockwise on to the syringe until it is fully attached.

- Slowly pull back the plunger and draw some air into the syringe.

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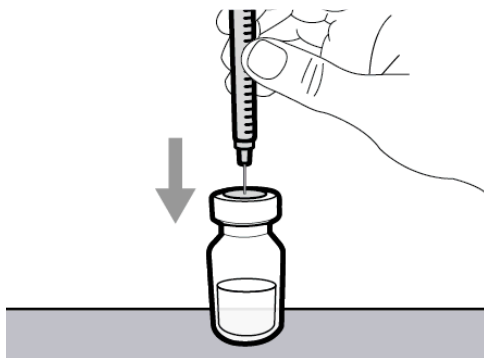
**Step D. Uncap transfer needle**



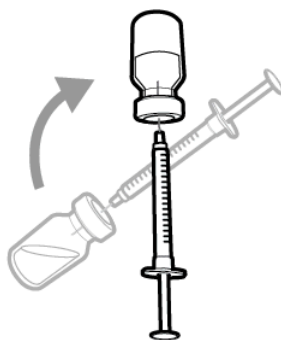
- Hold the syringe by the barrel with the transfer needle cap pointing up.
- Carefully pull the transfer needle cap straight off and away from your body. Do not throw the cap away. You will need to recap the transfer needle after drawing up the medicine.
- Do not touch the needle tip.

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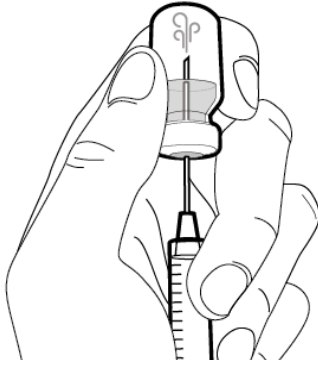
**Step E. Inject air into vial**



- With the new vial on the flat working surface, insert the new transfer needle and syringe, straight down into the centre of the vial stopper.

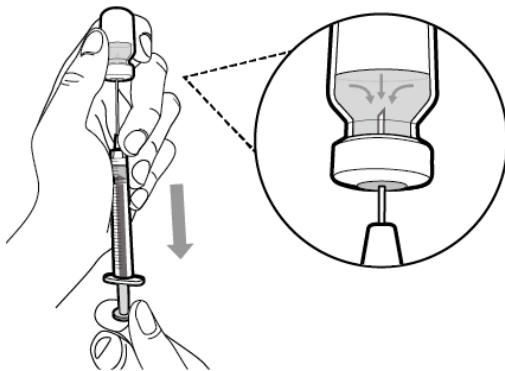


- Keep the transfer needle in the vial and turn the vial upside down.



- With the needle pointing upwards, inject the air from the syringe **above the medicine**.
- Keep your finger pressed down on the syringe plunger.
- Do not inject air into the medicine as this could create air bubbles in the medicine.

#### Step F. Transfer medicine to syringe



- Slide the tip of the needle down so that it is **within the medicine**.
- Slowly pull back the plunger to fill the syringe barrel more than the amount of medicine needed for your prescribed dose.
- Be careful not to pull the plunger out of the syringe.

**Note:** Ensure you have enough medicine in the syringe to complete your dose before moving onto the next step. If you cannot remove all of the medicine, turn the vial upright to reach the remaining amount.



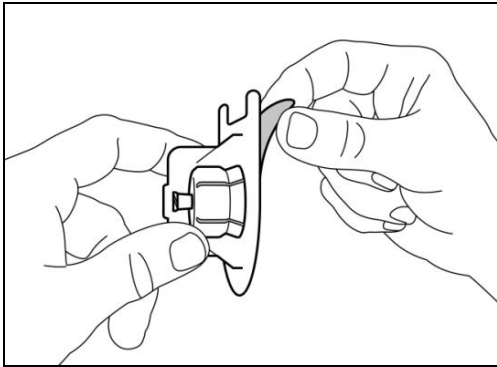
**Do not** use the transfer needle to inject medicine as this may cause harm such as pain and bleeding.

**Repeat steps A to F with each additional vial until you have more than your prescribed dose. Once completed, keep the transfer needle inserted in the vial and return to Step 6. Continue with the remaining steps.**

### Combining Vials using the VIAL ADAPTOR option

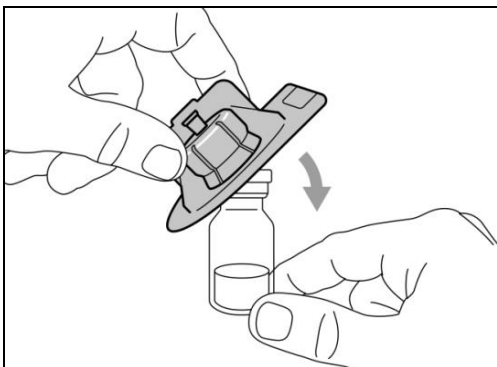
If you need to use more than 1 vial to get to your prescribed dose, follow these steps after you have drawn up the medicine from the first vial:

#### Step A. Insert new vial adaptor into new vial

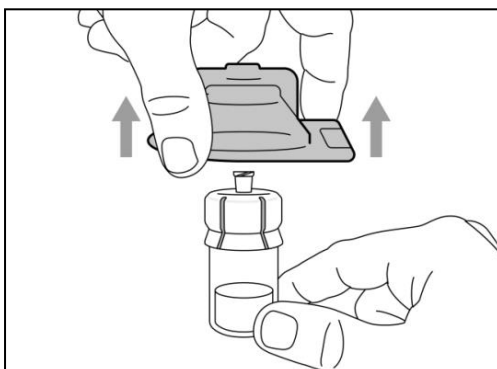


- Peel off back to open the blister pack.

**⚠ Do not remove the vial adaptor from the clear plastic blister pack.**

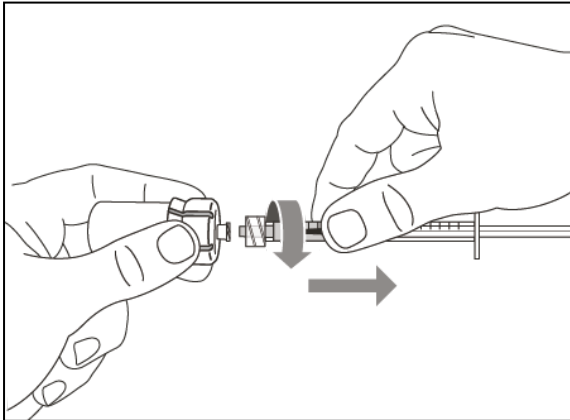


- Firmly press down the plastic blister pack with the vial adaptor onto the new vial at an angle, until you hear a 'click'.



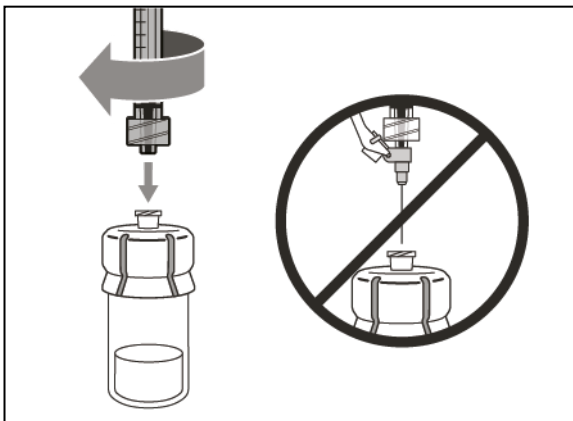
- Remove and throw away the plastic blister pack.
- **Do not** touch the tip of vial adaptor.

### Step B. Remove used vial adaptor



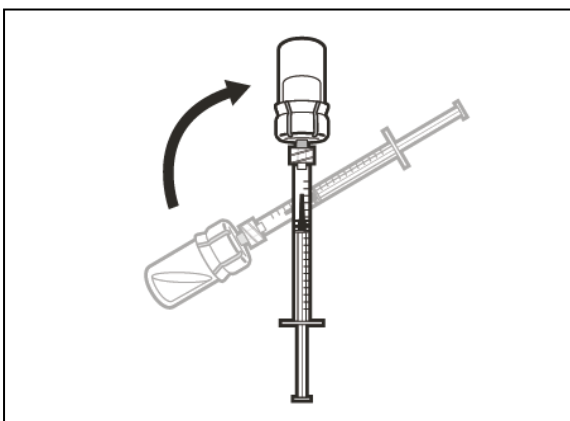
- Remove the used vial adaptor from the syringe by twisting anticlockwise and gently pulling.
- Throw away the used vial/vial adaptor into a sharps disposal container.

### Step C. Connect new vial adaptor to syringe

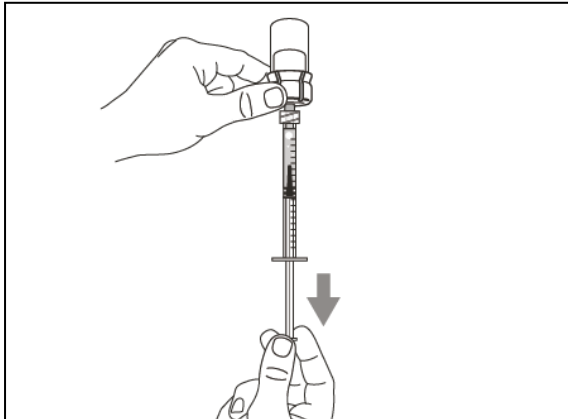


- **Push and twist the syringe clockwise** on to the vial adaptor until it is fully attached.

### Step D. Transfer medicine into syringe



- Keep the vial adaptor attached to the syringe and turn the vial upside down.



- With the syringe pointing upwards, slowly pull back the plunger to **fill the syringe with** more than the amount of **the medicine** needed for your prescribed dose.
- **Hold plunger firmly** to ensure it does not pull back in.
- Be careful not to pull the plunger out of the syringe.

**Note:** Ensure you have enough medicine in the syringe to complete your dose before moving on to the next step.

**Repeat steps A to D with each additional vial until you have more than the amount of medicine needed for your prescribed dose. Once completed, keep the vial adaptor onto the vial and return to Step 6 “Remove air bubbles”. Continue with the remaining steps.**

## Special Dosage Instructions

### *Paediatric use*

The safety and efficacy of Hemlibra have been established in paediatric patients. Use of Hemlibra in paediatric patients with haemophilia A (with or without FVIII inhibitors) is supported by three randomised studies and two single-arm studies.

These five clinical studies included a total of 137 paediatric patients in the following age groups: 61 adolescents (12 years to < 18 years), 71 children (2 years to < 12 years) and 5 infants (1 month to < 2 years). Safety and efficacy results were consistent with those observed for adults (see section 5.2).

The steady-state plasma trough concentrations of Hemlibra were comparable in adult and paediatric patients at equivalent weight-based doses (see section 5.2).

No dose adjustments are recommended in paediatric patients.

### ***Elderly use***

The safety and efficacy of Hemlibra have not been tested in an elderly population. Clinical studies of Hemlibra included 15 patients aged 65 and over. Relative bioavailability decreased with older age, but no clinically important differences were observed in the pharmacokinetics of Hemlibra between patients < 65 years and patients ≥ 65 years (see section 5.2).

No dose adjustments are recommended in patients ≥ 65 years of age (see section 5.2).

### ***Renal impairment***

The safety and efficacy of Hemlibra have not been tested in patients with renal impairment. There are limited data available on the use of Hemlibra in patients with mild to moderate renal impairment. No data are available on the use of Hemlibra in patients with severe renal impairment. Hemlibra is a monoclonal antibody and is cleared via catabolism rather than by renal excretion and a change in dose is not expected to be required for patients with renal impairment.

No dose adjustments are recommended in patients with renal impairment (see section 5.2).

### ***Hepatic impairment***

The safety and efficacy of Hemlibra have not been tested in patients with hepatic impairment. Patients with mild and moderate hepatic impairment were included in clinical trials. No data are available on the use of Hemlibra in patients with severe hepatic impairment. Hemlibra is a monoclonal antibody and is cleared via catabolism rather than by hepatic metabolism and a change in dose is not expected to be required for patients with hepatic impairment.

No dose adjustments are recommended in patients with hepatic impairment (see section 5.2).

## **4.3 Contraindications**

Hemlibra is contraindicated in patients with known hypersensitivity to emicizumab or to any of the excipients.

#### 4.4 Special warnings and precautions for use

##### **Thrombotic microangiopathy associated with Hemlibra and activated prothrombin complex concentrate**

Cases of thrombotic microangiopathy (TMA) were reported from a clinical trial in patients receiving Hemlibra prophylaxis when on average a cumulative amount of > 100 U/kg/24 hours of activated prothrombin complex concentrate (aPCC) for 24 hours or more were administered (see section 4.8). Treatment for the TMA events included supportive care with or without plasmapheresis and haemodialysis. Evidence of improvement was seen within one week following discontinuation of aPCC. This rapid clinical improvement is distinct from the usual clinical course observed in atypical haemolytic uremic syndrome and classic TMAs, such as thrombotic thrombocytopenic purpura, (see section 4.8).

Patients receiving Hemlibra prophylaxis should be monitored for the development of TMA when administering aPCC. The medical practitioner should immediately discontinue aPCC and interrupt Hemlibra therapy if clinical symptoms and/or laboratory findings consistent with TMA occur, and manage as clinically indicated. Medical practitioners should consider the risks of resuming Hemlibra prophylaxis following complete resolution of TMA on a case-by-case basis. In case a bypassing agent is indicated in a patient receiving Hemlibra prophylaxis, see below for dosing recommendations for the use of bypassing agents.

##### **Thromboembolism associated with Hemlibra and activated prothrombin complex concentrate**

Thrombotic events were reported from a clinical trial in patients receiving Hemlibra prophylaxis when on average a cumulative amount of > 100 U/kg/24 hours of aPCC for 24 hours or more were administered (see section 4.8). No cases required anticoagulation therapy, which is distinct from the usual treatment of thrombotic events. Evidence of improvement or resolution was seen after discontinuation of aPCC (see section 4.8).

Patients receiving Hemlibra prophylaxis should be monitored for the development of thromboembolism when administering aPCC. The medical practitioner should immediately

discontinue aPCC and interrupt Hemlibra therapy if clinical symptoms, imaging, and/or laboratory findings consistent with thrombotic events occur, and manage as clinically indicated. Medical practitioners should consider the risks of resuming Hemlibra prophylaxis following complete resolution of thrombotic events on a case-by-case basis. In case a bypassing agent is indicated in a patient receiving Hemlibra prophylaxis, see below for dosing recommendations for the use of bypassing agents.

### **Guidance on the use of bypassing agents in patients receiving Hemlibra prophylaxis**

Treatment with bypassing agents should be discontinued the day before starting Hemlibra therapy.

Medical practitioners should discuss with all patients and/or caregivers the exact dose and schedule of bypassing agents to use, if required while receiving Hemlibra prophylaxis.

Hemlibra increases the patients' coagulation potential. The bypassing agent dose required may therefore be lower than that used without Hemlibra prophylaxis. The dose and duration of treatment with bypassing agents will depend on the location and extent of bleeding and on the patient's clinical condition. Avoid use of aPCC unless no other treatment options/alternatives are available. If aPCC is indicated in a patient receiving Hemlibra prophylaxis, the initial dose should not exceed 50 U/kg. If bleeding is not controlled with the initial dose of aPCC up to 50 U/kg, additional aPCC doses should be administered under medical guidance or supervision, and the total aPCC dose should not exceed 100 U/kg in the first 24-hours of treatment. Treating medical practitioners must carefully weigh the risk of TMA and thromboembolism against the risk of bleeding when considering aPCC treatment beyond a maximum of 100 U/kg in the first 24-hours.

In clinical trials, no cases of thrombotic microangiopathy (TMA) or thrombotic events were observed with use of activated recombinant human FVII (rFVIIa) alone in patients receiving Hemlibra prophylaxis.

Bypassing agent dosing guidance should be followed for at least 6 months following discontinuation of Hemlibra prophylaxis (see section 5.2).





## Immunogenicity

Anti-hemlibra antibodies have been reported in a small number of patients treated with Hemlibra in clinical trials. Most patients found to have anti-hemlibra antibodies did not experience a change in Hemlibra plasma concentrations or an increase in bleeding events; however, in uncommon ( $\geq 1/1,000$  to  $< 1/100$ ) cases, the presence of neutralising anti-hemlibra antibodies with decreasing Hemlibra concentration may be associated with loss of efficacy (see section 4.8).

In case of clinical signs of loss of efficacy (e.g. increase in breakthrough bleeding events), prompt evaluation by a medical practitioner should be sought to assess the etiology and a possible change in treatment should be considered.

## Laboratory coagulation test interference

Hemlibra affects intrinsic pathway clotting-based laboratory tests, including the activated clotting time (ACT), activated partial thromboplastin time (aPTT) and all assays based on aPTT, such as one-stage factor VIII activity (see Table 1 below). Therefore, intrinsic pathway clotting-based laboratory test results in patients treated with Hemlibra prophylaxis should not be used to monitor Hemlibra activity, determine dosing for factor replacement or anti-coagulation, or measure factor VIII inhibitor titres. Laboratory tests affected and unaffected by Hemlibra are also shown in Table 1 below (see section 4.5).

**Table 1 Coagulation Test Results Affected and Unaffected by Hemlibra**

Results affected by Hemlibra	Results unaffected by Hemlibra
Activated partial thromboplastin time (aPTT)	Bethesda assays (bovine-chromogenic) for FVIII inhibitor titres
Bethesda assays (clotting-based) for FVIII inhibitor titres	Thrombin time (TT)
One-stage, aPTT-based, single-factor assays (e.g. FVIII activity)	One-stage, prothrombin time (PT)-based, single-factor assays
aPTT-based activated protein C	Chromogenic-based single-factor assays other than FVIII*



resistance (APC-R) Activated clotting time (ACT)	Immuno-based assays (e.g. ELISA, turbidimetric methods) Genetic tests of coagulation factors (e.g. Factor V Leiden, Prothrombin 20210)
*For important considerations regarding FVIII chromogenic activity assays, see Interactions.	

### ***Traceability***

In order to improve traceability of Hemlibra, the trade name and the batch number of the Hemlibra should be clearly recorded (or stated) in the patient file.

Advise patients/caregivers to record the batch number of the product whenever Hemlibra is administered outside of a healthcare setting.

### **4.5 Interaction with other medicines and other forms of interaction**

No adequate or well-controlled interaction studies have been conducted with Hemlibra.

Clinical experience suggests that a medicine interaction exists with Hemlibra and aPCC (see sections 4.3 and 4.8).

There is a possibility for hypercoagulability with rFVIIa or FVIII with Hemlibra based on preclinical experiments. Hemlibra increases coagulation potential, therefore the coagulation factor dose required to achieve haemostatis may be lower than when used without Hemlibra prophylaxis.

### ***Effect of Hemlibra on coagulation tests***

Hemlibra restores the tenase cofactor activity of missing activated factor VIII (FVIIIa). Coagulation laboratory tests based on intrinsic clotting (e.g. aPTT) measure the total clotting time including time needed for activation of FVIII to FVIIIa by thrombin. Such intrinsic pathway-based tests will yield overly shortened clotting times with Hemlibra, which does not require activation by thrombin. The overly shortened intrinsic clotting time will then disturb all single-

factor assays based on aPTT, such as the one-stage FVIII activity assay (see section 4.4, Table 1). However, single-factor assays utilising chromogenic or immuno-based methods are unaffected by Hemlibra and may be used to monitor coagulation parameters during treatment, with specific considerations for FVIII chromogenic activity assays as described below.

Chromogenic FVIII activity tests may be manufactured with either human or bovine coagulation proteins. Assays containing human coagulation factors are responsive to Hemlibra but may overestimate the clinical haemostatic potential of Hemlibra. In contrast, assays containing bovine coagulation factors are insensitive to Hemlibra (no activity measured) and can be used to monitor endogenous or infused factor VIII activity, or to measure anti-FVIII inhibitors.

Hemlibra remains active in the presence of inhibitors against factor VIII and so will produce a false-negative result in clotting-based Bethesda assays for functional inhibition of FVIII. Instead, a chromogenic Bethesda assay utilising a bovine-based FVIII chromogenic test that is insensitive to Hemlibra may be used.

Due to the long half-life of Hemlibra, effects on coagulation assays may persist for up to 6 months after the last dose (see section 5.2).

#### **4.6 Fertility, pregnancy and lactation**

Safety and efficacy has not been established.

##### **Pregnancy**

Safe use during pregnancy has not been established. It is not known whether Hemlibra can cause foetal harm when administered to a pregnant woman or can affect reproductive capacity. As antibodies, such as Hemlibra, crosses the placenta, pregnant women are advised not to use Hemlibra.

##### **Contraception**

Women of childbearing potential receiving Hemlibra should use effective contraception during, and for at least 6 months after cessation of Hemlibra treatment (see section 5.2).

##### **Lactation**

Women should not breastfeed while using Hemlibra.

#### 4.7 Effects on ability to drive and use machines

There is no evidence that treatment with Hemlibra results in an increase in adverse reactions that might lead to the impairment of the ability to drive and use machines.

#### 4.8 Undesirable effects

##### a) Summary of the safety profile

##### Clinical Trials

The following adverse drug reactions (ADRs) are based on pooled data from five phase III clinical trials (three adult and adolescent studies, a paediatric study, and an all-age group study [HAVEN 6]). A total of 444 patients with haemophilia A received at least one dose of Hemlibra as routine prophylaxis. Three hundred and seven (69,1 %) patients were adults (of which two were female) ( $\geq 18$  years), 61 (13, 7 %) were adolescents ( $\geq 12$  to  $< 18$  years), 71 (16,0 %) were children ( $\geq 2$  to  $< 12$  years) and five (1,1 %) were infants ( $\geq 1$  month to  $< 2$  years). The median duration of exposure across the studies was 32,0 weeks (range: 0,1 to 94,3 weeks).

Three patients (0,7 % in the pooled phase III clinical trials receiving Hemlibra prophylaxis) withdrew from treatment due to ADRs, which were thrombotic microangiopathy, skin necrosis contemporaneous with superficial thrombophlebitis, and headache.

##### b) Tabulated list of adverse reactions

Adverse drug reactions (ADRs) from the pooled phase III clinical trials in patients who received Hemlibra are listed by MedDRA system organ class (see Table 2 below). The corresponding frequency categories for each ADR are based on the following convention: very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $< 1/10$ ), and uncommon ( $\geq 1/1,000$  to  $< 1/100$ ).

**Table 2: Summary of Adverse Drug Reactions from Pooled Clinical Trials with Hemlibra**

System Organ Class	Number of patients	Percentage of patients	Frequency
ADR (preferred term, MedDRA)	(N = 444)		
<b>General disorders and administration site conditions</b>			
Injection site reactions	86	19,4 %	Very common



Pyrexia	23	5,2 %	Common
<b>Nervous system disorders</b>			
Headache	62	14,0 %	Very common
<b>Gastrointestinal disorders</b>			
Diarrhoea	21	4,7 %	Common
<b>Musculoskeletal and connective tissue disorders</b>			
Arthralgia	63	14,2 %	Very Common
Myalgia	13	2,94 %	Common
<b>Blood and Lymphatic system disorders</b>			
Thrombotic microangiopathy	3	< 1 %	Uncommon
<b>Infections and Infestations</b>			
Cavernous sinus thrombosis	1	<1 %	Uncommon
<b>Skin and subcutaneous tissue disorders</b>			
Skin necrosis	1	<1 %	Uncommon
<b>Vascular Disorders</b>			
Superficial thrombophlebitis	1	<1 %	Uncommon

## Post Marketing

The following adverse drug reactions have been identified from post marketing surveillance with Hemlibra (see Table 4). Adverse drug reactions from post marketing surveillance are listed by MedDRA system organ class.



**Table 4 Adverse Drug Reactions from Post marketing Surveillance**

System Organ Class	Frequency
ADR (preferred term, MedDRA)	
<b>Skin and subcutaneous tissue disorders</b>	
Angioedema <sup>a</sup>	Uncommon
Urticaria <sup>b</sup>	Common
Rash <sup>b</sup>	Common
<sup>a</sup> Frequency estimated at the upper limit of the 95 % confidence interval utilising the clinical trial safety population. <sup>b</sup> Frequency derived from clinical trial data.	

**c) Description of selected adverse drug reactions:**

The most serious adverse drug reactions reported from the pooled phase III clinical trials with Hemlibra were TMA and thrombotic events, including cavernous sinus thrombosis and superficial vein thrombosis contemporaneous with skin necrosis (see below and section 4.4).

**Thrombotic microangiopathy:**

In the pooled phase III clinical trials, thrombotic microangiopathy events were reported in < 1 % of patients (3/444) and in 9,7 % of patients (3/31) who received at least one dose of aPCC. Each patient was reported to have received on average a cumulative amount of > 100 U/Kg/24 hours of aPCC for 24 hours or more while receiving Hemlibra prophylaxis prior to the development of TMA events (presenting with thrombocytopenia, microangiopathic haemolytic anaemia, and acute kidney injury, without severe deficiencies in ADAMTS13 activity). One patient resumed Hemlibra following resolution of TMA without recurrence (see section 4.4).

**Thrombotic events:**

In the pooled phase III clinical trials, serious thrombotic events were reported in <1 % of patients (2/444) and in 6,5 % of patients (2/31) who received at least one dose of aPCC. Each patient was reported to have received on average a cumulative amount of > 100 U/Kg/24 hours of



aPCC for 24 hours or more while receiving Hemlibra prophylaxis, prior to the development of the thrombotic events. One patient resumed Hemlibra following resolution of the thrombotic event without recurrence (see section 4.4).

**Characterisation of aPCC Treatment (in the pooled phase III clinical trials)**

There were 82 instances of aPCC treatment\*, of which 8 instances (10 %) consisted of on average a cumulative amount of > 100 U/kg/24 hours of aPCC for 24 hours or more; two of the 8 instances were associated with thrombotic events and three of the 8 instances were associated with TMA (see Table 3). No TMA or thrombotic events were associated with the remaining instances of aPCC treatment. Of all instances of aPCC treatment, 68 % consisted of a single infusion ≤ 100 U/kg.

**Table 3 Characterisation of aPCC Treatment\* in the Pooled Phase III Clinical Trials**

Duration of aPCC treatment	Average cumulative amount of aPCC over 24 hours (U/Kg/24 hours)		
	< 50	50 – 100	> 100
< 24 hours	9	47	13
24-48 hours	0	3	1 <sup>a</sup>
> 48 hours	1	1	7 <sup>a, b, b, b</sup>

\* An instance of aPCC treatment is defined as all doses of aPCC received by a patient, for any reason, until there was a 36-hour treatment-free break. Includes all instances of aPCC treatment excluding those in the first 7 days and those that occurred 30 days after the discontinuation of Hemlibra.

<sup>a</sup> Thrombotic event

<sup>b</sup> Thrombotic microangiopathy

**Injection site reactions:**

Injection site reactions (ISRs) were reported very commonly (19,4 %) from clinical trials. All ISRs observed in the Hemlibra clinical trials were reported as being non-serious and generally mild to moderate in intensity, and 94,9 % resolved without treatment. The commonly reported

ISR symptoms were injection site erythema (10,6 %), injection site pruritus (2,9 %), injection site pain (4,1 %) and injection site swelling (2,7 %).

### ***Immunogenicity***

In the pooled phase III clinical trials with Hemlibra, development of neutralising anti-hemlibra antibodies associated with decreasing emicizumab concentration was uncommon. One patient, who developed neutralising anti-hemlibra antibodies with decreasing emicizumab concentration, experienced loss of efficacy (manifest as breakthrough bleeding) after 5 weeks of treatment and later discontinued Hemlibra treatment (see section 4.4). Overall, the safety profile of Hemlibra was similar between those patients with anti-hemlibra antibodies (including neutralising antibodies) and those without.

### ***Patients with mild or moderate haemophilia A without FVIII inhibitors (HAVEN 6)***

The safety profile of Hemlibra in patients with mild or moderate haemophilia A without FVIII inhibitors (HAVEN 6) was consistent with the known safety profile in previous HAVEN studies, conducted primarily in patients with severe haemophilia A with or without FVIII inhibitors. There were no new adverse drug reactions reported.

## **4.9 Overdose**

Accidental overdose may result in hypercoagulability.

Patients who receive an accidental overdose should immediately contact their medical practitioner/ medicine control centre and be monitored closely.

Treatment should be symptomatic and supportive.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**



Pharmacotherapeutic group: anti-haemorrhagics, other systemic haemostatics; ATC code: B02BX06.

Emicizumab bridges activated factor IX and factor X to restore the function of missing activated factor VIII that is needed for effective haemostasis.

Emicizumab has no structural relationship or sequence homology to factor VIII and, as such, does not induce or enhance the development of direct inhibitors to factor VIII.

Prophylactic therapy with emicizumab shortens the activated partial thromboplastin time (aPTT) and increases the reported FVIII activity (using a chromogenic assay with human coagulation factors). These two pharmacodynamic markers do not reflect the true haemostatic effect of emicizumab *in vivo* (aPTT is overly shortened and reported FVIII activity may be overestimated) but provide a relative indication of the pro-coagulant effect of emicizumab.

## **CLINICAL EFFICACY**

### **HAVEN 6**

*Patients (all ages) with mild or moderate haemophilia A without FVIII inhibitors*

The HAVEN 6 study was a multicenter, open-label, single-arm study in 71 emicizumab-treated patients (all ages) with mild (n = 20 [28,2 %]) or moderate (n = 51 [71,8 %]) haemophilia A without FVIII inhibitors for whom prophylaxis was indicated, as assessed by the investigator. Most patients were male (69 patients [97,2 %]), and 2 were female (2,8 %). At study entry, 34 patients (47,9 %) were on episodic and 37 patients (52,1 %) were on prophylactic treatment with FVIII. Patients received subcutaneous emicizumab, 3 mg/kg once weekly for the first four weeks followed by patient preference for one of the following maintenance regimens, from week 5: 1,5 mg/kg once weekly (n = 24 [33,8 %]), 3 mg/kg every two weeks (n = 39 [54,9 %]) or 6 mg/kg every four weeks (n = 8 [11,3 %]), thereafter. Dose up-titration was allowed after 24 weeks for patients who experienced two or more qualified bleeds (i.e., spontaneous and clinically significant bleeds occurring at steady state). At the time of interim analysis, no patients underwent up-titration of their maintenance dose.

The primary efficacy objective of the study was to evaluate the efficacy of emicizumab prophylaxis based on the number of bleeds requiring treatment with coagulation factors over time (i.e., bleed rate of treated bleeds, see Table 5). Other objectives were to evaluate the efficacy of emicizumab prophylaxis based on the number of all bleeds, spontaneous bleeds, joint bleeds, and target joint bleeds over time, as well as assessing patient reported health-related quality of life HRQoL with the Comprehensive Assessment Tool of Challenges in Haemophilia (CATCH) questionnaire over time.

### **Efficacy results**

#### HAVEN 6 (interim analysis)

Interim efficacy results for the HAVEN 6 clinical study are summarised below. In the study, 71 patients aged 2 to 71 years old were evaluated for efficacy with a median observation time of 27,6 weeks (range: 6,7 – 61,7 weeks). The efficacy results of emicizumab prophylaxis in patients with mild or moderate haemophilia A without FVIII inhibitors with respect to rate of treated bleeds, all bleeds, treated spontaneous bleeds, treated joint bleeds, and treated target joint bleeds are shown in Table 5.

	<sup>c</sup> Hemlibra 1,5 mg/kg QW, 3 mg/kg Q2W or 6 mg/kg Q4W		
<b>Endpoints</b>	<sup>a</sup> ABR (95 % CI)	<sup>b</sup> Median ABR (IQR)	% Zero Bleeds (95 %CI)
N	71	71	71
Treated Bleeds	0,8 [0,41;1,46]	0,0 [0,00; 0,00]	80,3 [69,1; 88,8]
All Bleeds	2,7 [1,87; 3,83]	1,7 [0,00; 3,80]	45,1 [33,2; 57,3]
Treated Spontaneous Bleeds	0,1 [0,02;0,23]	0,0 [0,00; 0,00]	95,8 [88,1; 99,1]
Treated Joint Bleeds	0,3 [0,12;0,65]	0,0 [0,00; 0,00]	90,1 [80,7; 95,9]
Treated Target Joint	*Did not converge	0,0 [0,00; 0,00]	94,4 [86,2; 98,4]



Bleeds			
<p><sup>a</sup> Calculated with negative binomial regression (NBR) model</p> <p><sup>b</sup> Calculated ABR</p> <p>Bleed definitions adapted based on ISTH criteria</p> <p>Treated bleeds: bleeds treated with FVIII.</p> <p>All bleeds: bleeds treated and not treated with FVIII.</p> <p>Patients exposed to emicizumab started with a loading dose of 3 mg/kg/week for 4 weeks.</p> <p>ABR=Annualized Bleed Rate, CI=confidence interval; IQR=interquartile range; 25<sup>th</sup> percentile to 75<sup>th</sup> percentile; QW=once every week; Q2W=once every two weeks; Q4W=once every four weeks prophylaxis</p> <p><sup>c</sup> 1,5 mg/kg QW (n = 24); 3 mg/kg Q2W, (n = 39); 6 mg/kg Q4W (n = 8)</p> <p>*Model may not converge due to too short follow-up times combined with a low number of bleeds</p>			

**Health-related outcome measures**

HAVEN 6 assessed HRQoL in adult and paediatric patients, as well as caregivers of paediatric patients, using the CATCH questionnaire. The domains of risk perception and impact of hemophilia on daily activities, social activities, recreational activities, and work/school, as well as preoccupation and treatment burden were examined.

**Health-related outcomes results**

**HAVEN 6 health-related outcomes**

In HAVEN 6, HRQoL for patients with mild or moderate haemophilia A of all ages was evaluated at week 25 based on the CATCH questionnaire. The CATCH questionnaire (version 1.0) is a validated instrument that assesses the effect of haemophilia and its treatment. Different versions of the questionnaire exist for adult patients, paediatric patients and caregivers of paediatric patients. HRQoL on Hemlibra prophylaxis remained generally stable, with

improvement in the treatment burden domain of CATCH consistently observed across the respondent group.

## 5.2 Pharmacokinetic properties

The pharmacokinetics of emicizumab were determined via a non-compartmental analysis in healthy subjects and using a population pharmacokinetic analysis on a database composed of 389 patients with haemophilia A.

### Absorption

Following subcutaneous administration in haemophilia A patients, the absorption half-life was 1,6 days.

Following multiple subcutaneous administrations of 3 mg/kg once weekly for the first 4 weeks in haemophilia A patients, mean ( $\pm$ SD) trough plasma concentrations of emicizumab achieved  $52,6 \pm 13,6 \mu\text{g/mL}$  at Week 5. Sustained mean trough plasma concentrations of emicizumab at steady-state were  $51,2 \mu\text{g/mL}$ ,  $46,9 \mu\text{g/mL}$  and  $38,5 \mu\text{g/mL}$  with the recommended maintenance doses of 1,5 mg/kg once weekly, 3 mg/kg every two weeks or 6 mg/kg every four weeks, respectively (see Figure 1).

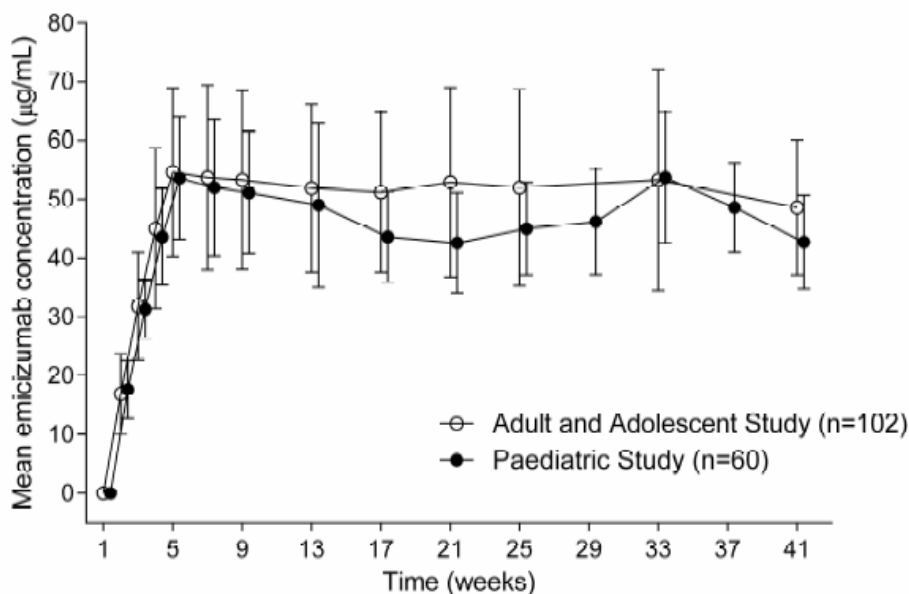
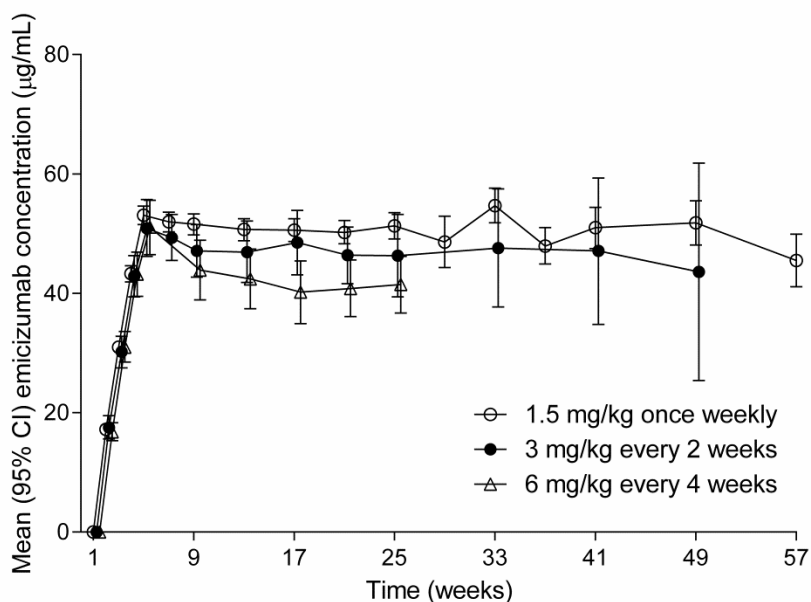


Figure 1: Mean ( $\pm$ 95 % CI) Emicizumab Trough Concentrations for Maintenance Doses



The mean ( $\pm$ SD)  $C_{trough}$ ,  $C_{max}$  and ratios of  $C_{max}/C_{trough}$  at steady-state for the recommended maintenance doses of 1,5 mg/kg once weekly, 3 mg/kg every two weeks or 6 mg/kg every four weeks are shown in below.

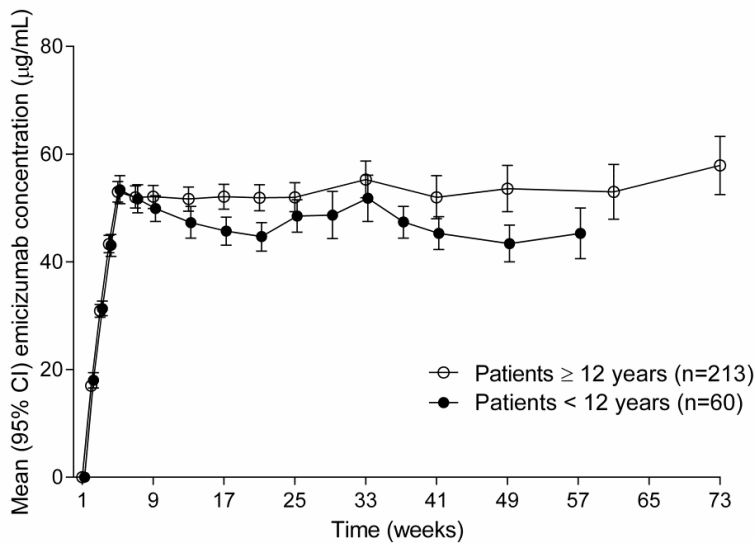


### Mean ( $\pm$ SD) Steady-State Emicizumab Concentrations

	Maintenance Dose		
Parameters	1,5 mg/kg once weekly	3 mg/kg every two weeks	6 mg/kg every four weeks
$C_{max, ss}$ ( $\mu\text{g/mL}$ )	55,1 $\pm$ 15,9	58,3 $\pm$ 16,4	67,0 $\pm$ 17,7
$C_{avg, ss}$ ( $\mu\text{g/mL}$ )	53,7 $\pm$ 15,6	53,7 $\pm$ 15,6	53,7 $\pm$ 15,6
$C_{trough, ss}$ ( $\mu\text{g/mL}$ )	51,2 $\pm$ 15,2	46,9 $\pm$ 14,8	38,5 $\pm$ 14,2
$C_{max}/C_{trough}$ ratio	1,08 $\pm$ 0,03	1,26 $\pm$ 0,12	1,85 $\pm$ 0,47
$C_{avg, ss}$ = average concentration at steady state; $C_{max, ss}$ = maximum plasma concentration at steady state; $C_{trough, ss}$ = trough concentration at steady state; Pharmacokinetic parameters derived from the population PK model.			

Similar PK profiles were observed following once weekly dosing (3 mg/kg/week for 4 weeks followed by 1,5 mg/kg/week) in adults/adolescents ( $\geq 12$  years) and children ( $< 12$  years) (see Figure 2).

**Figure 2: Mean Plasma Emicizumab Concentration versus Time Profiles for Patients  $\geq 12$  Years Compared with Patients  $<12$  Years**



In healthy subjects, the absolute bioavailability following subcutaneous administration of 1 mg/kg was between 80,4 % and 93,1 % depending on the injection site. Similar pharmacokinetic profiles were observed following subcutaneous administration in the abdomen, upper arm, and thigh. Emicizumab can be administered interchangeably at these anatomical sites (see section 4.2).

### Distribution

Following a single intravenous dose of 0,25 mg/kg emicizumab in healthy subjects, the volume of distribution at steady state was 106 mL/kg (i.e. 7,4 L for a 70 kg adult). Emicizumab is not intended for intravenous use (see section 4.2).

The apparent volume of distribution (V/F), estimated from the population pharmacokinetic analysis, in haemophilia A patients following multiple subcutaneous doses of emicizumab was 10,4 L.

## **Metabolism**

The metabolism of emicizumab has not been studied. IgG antibodies are mainly catabolised by lysosomal proteolysis and then eliminated from or reused by the body.

## **Elimination**

Following intravenous administration of 0,25 mg/kg in healthy subjects, the total clearance of emicizumab was 3,26 mL/kg/day (i.e. 0,228 L/d for a 70 kg adult) and the mean terminal half-life was 26,7 days.

Following single subcutaneous injection in healthy subjects, the elimination half-life was approximately 4 to 5 weeks.

Following multiple subcutaneous injections in haemophilia A patients, the apparent clearance was 0,271 L/day and the elimination apparent half-life was 26,9 days.

## **Dose linearity**

Emicizumab exhibited dose-proportional pharmacokinetics in patients with haemophilia A over a dose range from 0,3 to 6 mg/kg once weekly following subcutaneous administration.

## **Pharmacokinetics in Special Populations**

### **Renal impairment**

No studies on the effect of renal impairment on the pharmacokinetics of emicizumab have been conducted. Most of the patients with haemophilia A in the population pharmacokinetic analysis had normal renal function (N = 332; creatinine clearance [CLcr]  $\geq$  90 mL/min) or mild renal impairment (N = 27; CLcr of 60-89 mL/min). Only 2 patients had moderate renal impairment (CLcr of 30-59 mL/min). No patients had severe renal impairment. Mild or moderate renal impairment did not appear to have an impact on the pharmacokinetics of emicizumab (see section 4.2)

### **Hepatic impairment**

No studies on the effect of hepatic impairment on the pharmacokinetics of emicizumab have been conducted.



## Paediatrics

The effect of age on the pharmacokinetics of emicizumab was assessed in a population pharmacokinetic analysis which included 5 infants ( $\geq 1$  month to  $< 2$  years, 55 children ( $\geq 2$  years to  $< 12$  years) and 50 adolescents (12 -  $< 18$  years) with haemophilia A. Age did not affect the pharmacokinetics of emicizumab in paediatric patients (see section 4.2).

## Elderly

The effect of age on the pharmacokinetics of emicizumab was assessed in a population pharmacokinetic analysis which included 13 patients aged 65 years and older (no subjects were older than 77 years of age). Relative bioavailability decreased with older age, but no clinically important differences were observed in the pharmacokinetics of emicizumab between patients  $< 65$  years and patients  $\geq 65$  years.

## Gender

Limited data in female patients suggests that gender did not affect the pharmacokinetics of emicizumab.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

L-arginine

L-aspartic acid

L-histidine

Polaxamer 188

Water for injection

### 6.2 Incompatibilities

No incompatibilities between Hemlibra and polypropylene or polycarbonate syringes, polycarbonate vial adapters and stainless steel needles have been observed.

In the absence of compatibility studies, Hemlibra must not be mixed with other medicines.



### 6.3 Shelf life

Hemlibra® 30 mg/1 mL: 24 months

Hemlibra® 60 mg/0,4 mL: 24 months

Hemlibra® 105 mg/0,7 mL: 24 months

Hemlibra® 150 mg/1 mL: 24 months

Once removed from the refrigerator, unopened vials can be kept at room temperature (below 30 °C) for up to 7 days.

After storage at room temperature, unopened vials may be returned to the refrigerator.

Cumulative storage time at room temperature should not exceed 7 days.

Once transferred from the vial to the syringe Hemlibra should be used immediately since it does not contain any antimicrobial preservative.

Refer to the Hemlibra “Instructions for Use” for handling instructions when combining vials in a syringe. Do not use different Hemlibra vial concentrations (30 mg/mL and 150 mg/mL) in a single syringe when combining vials to administer the prescribed dose.

### 6.4 Special precautions for storage

Store vial in a refrigerator at 2 - 8 °C.

Do not freeze. Do not shake.

Keep vial in the outer carton in order to protect from light.

Store out of reach of children.

Do not use after the expiry date (EXP) shown on the pack.

#### *Disposal of unused/expired medicines*

Hemlibra should not be disposed of via wastewater and disposal through household waste should be avoided.

### 6.5 Nature and contents of container

Hemlibra is supplied in single-use 3 mL clear glass vial containing:

- 1 mL of Hemlibra solution (30 mg/mL),

- 0,4 mL of Hemlibra solution (150 mg/mL),
- 0,7 mL of Hemlibra solution (150 mg/mL),
- 1 mL of Hemlibra solution (150 mg/mL).

Each pack of Hemlibra contains 1 glass vial.

Once transferred from the vial to the syringe, Hemlibra should be used immediately.

Not all strengths may be marketed.

## **6.6 Special precautions for disposal and other handling**

Hemlibra solution is a sterile, preservative-free, and ready to use solution for subcutaneous injection that does not need to be diluted. Hemlibra solution should be discarded if particulate matter is visible or the product is discoloured.

- Once removed from the refrigerator, unopened vials can be kept at room temperature (below 30 °C) for up to 7 days.
- After storage at room temperature, unopened vials may be returned to the refrigerator. Cumulative storage time at room temperature should not exceed 7 days.
- Once transferred from the vial to the syringe Hemlibra should be used immediately.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g toilets).

A syringe, a transfer needle with filter or a transfer needle or a vial adaptor and an injection needle are needed to withdraw Hemlibra solution from the vial and inject it subcutaneously.

## **7. HOLDER OF THE CERTIFICATE OF REGISTRATION**

Roche Products (Pty) Ltd

90 Bekker Road, Hertford Office Park,

Building E, Vorna Valley, Midrand,

Johannesburg, 1686

South Africa

Roche Ethical Assistance Line (REAL) toll-free: 0800 21 21 25



## 8. REGISTRATION NUMBERS

Hemlibra® 30 mg/1 mL solution for injection: 53/30.1/0071

Hemlibra® 60 mg/0,4 mL solution for injection: 53/30.1/0072

Hemlibra® 105 mg/0,7 mL solution for injection: 53/30.1/0073

Hemlibra® 150 mg/1 mL solution for injection: 53/30.1/0074

## 9. DATE OF FIRST AUTHORISATION

Date of registration: 9 May 2019

## 10. DATE OF REVISION OF THE TEXT

16 July 2024

Hemlibra® 30 mg/1 mL:	Namibia: NS2 19/30/0033	Zimbabwe: PP 2019/10.7/5815	Botswana: S2 BOT2103738
Hemlibra® 60 mg/0,4 mL:	Namibia: NS2 19/30/0034	Zimbabwe: PP 2019/10.7/5814	Botswana: S2 BOT2103737
Hemlibra® 105 mg/0,7 mL:	Namibia: NS2 19/30/0035	Zimbabwe: PP 2019/10.7/5813	Botswana: S2 BOT2103736
Hemlibra® 150 mg/1 mL:	Namibia: NS2 19/30/0036	Zimbabwe: PP 2019/10.7/5812	Botswana: S2 BOT2103730

### Approved manufacturer(s):

Chugai Pharma Manufacturing Co., Ltd. (CPMC)  
16-3, Kiyohara Kogyodanchi  
Utsunomiya City, Tochigi,  
321-3231 Japan



## PATIENT INFORMATION LEAFLET

### **WARNING: THROMBOTIC MICROANGIOPATHY and THROMBOEMBOLISM**

Cases of thrombotic microangiopathy and thrombotic events were reported when on average a cumulative amount of >100 U/kg/24 hours of activated prothrombin complex concentrate was administered for 24 hours or more to patients receiving Hemlibra prophylaxis. Monitor for the development of thrombotic microangiopathy and thrombotic events if activated prothrombin complex concentrate (aPCC) is administered. Discontinue aPCC and suspend dosing of Hemlibra if symptoms occur. Safety data limited and are being monitored.

### **SCHEDULING STATUS**

**S4**

**Hemlibra® 30 mg/1 mL** solution for injection

**Hemlibra® 60 mg/0,4 mL** solution for injection

**Hemlibra® 105 mg/0,7 mL** solution for injection

**Hemlibra® 150 mg/1 mL** solution for injection

Sugar free

### **Read all of this leaflet carefully before you start using Hemlibra**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- Hemlibra has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### **What is in this leaflet**

1. What Hemlibra is and what it is used for
2. What you need to know before you are given Hemlibra

3. How to use Hemlibra
4. Possible side effects
5. How to store Hemlibra
6. Contents of the pack and other information
7. Instructions for use

## 1. What Hemlibra is and what it is used for

### What Hemlibra is

Hemlibra belongs to a group of medicines called “monoclonal antibodies”. Monoclonal antibodies are a type of protein that recognises and binds to a target in the body.

### What Hemlibra is used for

Hemlibra is used for treating patients of all ages with:

- either haemophilia A who have developed factor VIII inhibitors
- or with severe haemophilia A who have not developed factor VIII inhibitors (the FVIII blood level is less than 1 %).

Haemophilia A is an inherited condition caused by a lack of factor VIII, an essential substance required for blood to clot and stop any bleeding.

Hemlibra prevents bleeding or reduces bleeding episodes in people with this condition.

Some patients with haemophilia A can develop factor VIII inhibitors (antibodies against factor VIII) which stop the replacement factor VIII from working.

### How Hemlibra works

Hemlibra restores the function of missing factor VIII that is needed for effective blood clotting. Its structure is different from factor VIII, therefore Hemlibra is not affected by factor VIII inhibitors.

## 2. What you need to know before you use Hemlibra

### Hemlibra should not be administered to you:

If you are hypersensitive (allergic) to emicizumab or any of the other ingredients of Hemlibra.

### Warnings and precautions



**Before you start using Hemlibra, it is very important you talk to your doctor about when and how to use “bypassing agents” while receiving Hemlibra, as this may differ from before.** Examples of bypassing agents include “activated prothrombin complex concentrate” (aPCC, also called FEIBA) and “recombinant FVIIa” (rFVIIa, also called NovoSeven). Serious and potentially life-threatening side effects have been observed when aPCC (FEIBA) was used in patients who were also receiving Hemlibra.

**Be aware of the potentially serious side effects of using activated prothrombin complex concentrate (aPCC) (FEIBA) while receiving Hemlibra (see “Possible side effects”).**

- **Destruction of red blood cells (thrombotic microangiopathy)**

- thrombotic microangiopathy is a serious and potentially life-threatening condition,
- when people have thrombotic microangiopathy, the lining of the blood vessels can be damaged and blood clots may develop in small blood vessels. This can cause damage to the kidneys and/or other organs,
- it is important to know the symptoms of thrombotic microangiopathy, in case you develop the condition (see “Possible side effects” for a list of symptoms).

**Stop using Hemlibra and activated prothrombin complex concentrate (aPCC) (FEIBA), and talk to a doctor immediately** if you or your caregiver notices any symptoms of thrombotic microangiopathy.

- **Blood clots (thromboembolism)**

- blood clots may form. A blood clot can block blood vessels and may be life-threatening
- it is important to know the symptoms of blood clots, in case clots develop (see “Possible side effects” for a list of symptoms)

**Stop using Hemlibra and activated prothrombin complex concentrate (aPCC) (FEIBA), and talk to a doctor immediately** if you or your caregiver notices any symptoms of blood clots.

### **Antibody formation (immunogenicity)**

- in uncommon cases, you can develop antibodies to this medicine and it may then stop working for you.
- you may notice that bleeding is not being controlled with your prescribed dose of this medicine.

**Talk to a doctor immediately** if you or your caregiver notices that Hemlibra has stopped working for you (e.g. an increase in bleeds). Your doctor may need to change your treatment if Hemlibra stops working for you.

### **Children below the age of 1 year**

In children less than one year of age, the blood system is still developing. If your child is less than one year old, your doctor may prescribe Hemlibra only after carefully weighing the expected benefits and risks of using this product.

### **Other medicines and Hemlibra**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

- **Using a bypassing agent while receiving Hemlibra**

- **Before you start using Hemlibra, talk to your doctor and carefully follow their instructions regarding when to use a bypassing agent and the dose and schedule you should use.**

Hemlibra increases the ability of your blood to clot. Therefore, the dose of bypassing agent required may be lower than the dose you used prior to starting Hemlibra.

- **Avoid using activated prothrombin complex concentrate (aPCC) (FEIBA)** unless no other treatment options are available. However, if aPCC (FEIBA) is required, talk to your doctor in case you feel you need more than 50 units/kg of aPCC (FEIBA) total. For more information on using aPCC (FEIBA) while receiving Hemlibra, see “What you need to know before you use Hemlibra”, be aware of the potentially serious side effects of using aPCC (FEIBA) while receiving Hemlibra.

-

## Laboratory tests

Tell your doctor if you are using Hemlibra before you have laboratory tests that measure how well your blood is clotting. This is because the presence of Hemlibra in the blood may interfere with some of these laboratory tests, leading to inaccurate results.

## Pregnancy and breastfeeding

If you are pregnant, if you think you are pregnant, if you are planning to have a baby or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before being given Hemlibra.

- Do not use Hemlibra if you are pregnant. Your doctor will discuss the risk to your baby.
- You should use an effective method of birth control (contraception) during treatment with Hemlibra and for 6 months after your last injection of Hemlibra.
- Do not breastfeed your baby while on treatment with Hemlibra.

## Driving and using machines

Hemlibra is not likely to affect your ability to drive or use machines.

### 3. How to use Hemlibra

A medical practitioner qualified to care for patients with haemophilia will start you on treatment with Hemlibra. Always use Hemlibra exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Each time you use Hemlibra, record the name and batch number of the medicine.

## How much Hemlibra to use

### *First dose*





- Weeks 1 to 4: The dose is 3 milligrams for every 1 kilogram you weigh, injected under the skin (subcutaneously) once a week.

### ***Maintenance doses***

From week 5 and onwards: The dose of Hemlibra is dependent on your weight and your doctor should tell you how much to inject. The dose is either:

- 1,5 mg/kg once weekly, or
- 3 mg/kg every two weeks, or
- 6 mg/kg every four weeks

### **How Hemlibra is given**

**If you or your caregiver gives an injection of Hemlibra, you must carefully read and follow the instructions under “Instructions for use” below.**

- Hemlibra is given by injection under the skin (subcutaneously)
- Your doctor or nurse will show you and/or your caregiver how to inject Hemlibra
- Once you and/or your caregiver have been trained, you should be able to inject this medicine at home, by yourself or with the help of a caregiver
- Do not inject Hemlibra into a vein or muscle. To correctly insert the needle under the skin, pinch a fold of loose skin at the clean injection site with your free hand. Pinching the skin is important to ensure that you inject under the skin (into fatty tissue) but not any deeper (into muscle). Injecting into a muscle could result in an uncomfortable injection
- Prepare and give the injection under clean and germ-free conditions using “aseptic technique”. You will be given more information about this by your doctor or nurse
- Before using Hemlibra, check the solution for particles or discolouration. The solution should be colourless to slightly yellow. Do not use Hemlibra if you notice that it is cloudy, discoloured, or contains visible particles.

### **Where to inject Hemlibra**



- your doctor will show you and/or your caregiver which areas of the body should be injected with Hemlibra,
- the recommended places to give an injection are: the front of the waist (lower abdomen), upper outer arms, or the front of the thighs. Only give an injection in the recommended places,
- each time you or your caregiver gives an injection, use a different area of the body to the one you used before, using one of the recommended places (front of the waist, upper outer arms, or the front of the thighs),
- do not give injections where the skin is red, bruised, tender, hard, or areas where there are moles or scars,
- when using Hemlibra, other medicines injected under the skin should be given in a different area.

### **Using syringes and needles**



- a syringe, a transfer needle with filter or transfer needle, and an injection needle are needed to withdraw the Hemlibra solution from the vial into the syringe and inject it under the skin,
- syringes, transfer needles with filter, transfer needles, and injection needles are not provided in this pack. For more information, see “What Hemlibra looks like and contents of the pack”, what is needed for Hemlibra administration and is not contained in this pack,
- make sure that you use a new injection needle for each injection and dispose of it after a single use,
- a 1 mL syringe should be used for an injection up to 1 mL of Hemlibra solution.
- a 2 to 3 mL syringe should be used for an injection greater than 1 mL and up to 2 mL of Hemlibra solution.
- when used together with a vial adaptor, a low dead space plunger syringe must be used.

Your doctor will tell you how long your treatment with Hemlibra will last. Do not stop treatment without consulting with your doctor. If you have the impression that the effect of Hemlibra is too strong or too weak, tell your doctor or pharmacist.

### **Use in children and adolescents**

Hemlibra can be used in children and adolescents of all ages (for the recommended dose, see “How to use Hemlibra”).

If a child would like to self-inject the medicine, the child’s healthcare provider and the parent or caregiver should agree on whether it is appropriate for them to do so. Self-injection for children below the age of 7 years is not recommended.

### **If you take more Hemlibra than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you or your caregiver uses more Hemlibra than you are supposed to, tell your doctor immediately. This is because you may be at risk of developing side effects such as blood clots. Always use Hemlibra exactly as your doctor has told you, and check with your doctor, pharmacist or nurse if you are not sure.



### **If you forget to take Hemlibra**

If you forget your scheduled weekly injection, inject the forgotten dose as soon as possible approximately 24 hours before the day of the next scheduled dose. Then, continue to inject the medicine once a week as scheduled. Do not inject a double dose to make up for a forgotten dose.

If you are not sure what to do, ask your doctor, pharmacist or nurse.

### **If you stop taking Hemlibra**

Do not stop using Hemlibra without talking to your doctor. If you stop using Hemlibra, you may no longer be protected against bleeding.

If you have any further questions on the use of Hemlibra, ask your doctor, pharmacist or nurse.

## **4. Possible side effects**

Hemlibra can have side effects.

Not all side effects reported for Hemlibra are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Hemlibra please consult your doctor, pharmacist or healthcare professional for advice.

### **Serious side effects of using activated prothrombin complex concentrate (aPCC) (FEIBA) while receiving Hemlibra**

**Stop using Hemlibra and aPCC (FEIBA) and talk to a doctor immediately** if you or your caregiver notices any of the following side effects:

- **Destruction of red blood cells (thrombotic microangiopathy):**
  - confusion

- weakness,
- swelling of arms and legs,
- yellowing of skin and eyes,
- vague abdominal or back pain, feeling sick (nausea),
- being sick (vomiting) or
- urinating less

These symptoms may be signs of thrombotic microangiopathy.

• **Blood clots (thromboembolism):**

- swelling, warmth, pain or redness – these symptoms may be signs of a blood clot in a vein near the surface of the skin,
- headache, numbness in your face, eye pain or swelling or vision impairment – these symptoms may be signs of a blood clot in a vein behind your eye,
- blackening of the skin – this symptom may be a sign of severe damage to the skin tissue.

**Stop using Hemlibra and activated prothrombin complex concentrate (aPCC) (FEIBA) and talk to a doctor immediately** if you or your caregiver notices any of the side effects listed above.

**Other side effects when using Hemlibra**

**Frequent:**

- headache
- joint pain
- a reaction in the area the injection was given (redness, itching, pain)
- fever
- muscle aches
- diarrhoea
- thrombotic microangiopathy (damage to blood vessels)
- itchy rash or hives (urticaria)
- rash

**Less frequent:**

- blood clot in a vein behind your eye (cavernous sinus thrombosis)
- severe damage of the skin tissue (skin necrosis)
- blood clot in a vein near the surface of the skin (superficial thrombophlebitis)
- swollen face, tongue and/or throat and/or difficulty in swallowing, or hives, together with difficulty in breathing which are suggestive of an angioedema

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Hemlibra.

**5. How to store Hemlibra**

- Store all medicines out of reach of children.
- Store vial in a refrigerator at 2 °C - 8 °C.
- Do not freeze. Do not shake.
- Keep vial in the outer carton in order to protect from light.
- Do not use Hemlibra after the expiry date (EXP) shown on the pack.
- Once removed from the refrigerator, unopened vials can be kept at room temperature (below 30 °C) for up to 7 days.
- After storage at room temperature, unopened vials may be returned to the refrigerator. Cumulative storage time at room temperature should not exceed 7 days.
- Once transferred from the vial to the syringe Hemlibra should be used immediately.
- Return all unused medicine to your pharmacist.



- Do not dispose of unused medicine in drains or sewerage systems (e.g toilets).

## 6. Contents of the pack and other information

### What Hemlibra contains

- The active substance is emicizumab. Each vial of Hemlibra contains 30 mg (1 mL at a concentration of 30 mg/mL), 60 mg (0,4 mL at a concentration of 150 mg/mL), 105 mg (0,7 mL at a concentration of 150 mg/mL) or 150 mg (1 mL at a concentration of 150 mg/mL) of emicizumab.
- The other ingredients are L-arginine, L-aspartic acid, L-histidine, poloxamer 188 and water for injection.

### What Hemlibra looks like and contents of the pack

Hemlibra solution is a colourless to slightly yellow sterile, preservative-free, and ready to use solution for subcutaneous injection that does not need to be diluted. Hemlibra solution should be discarded if particulate matter is visible or product is discoloured.

Hemlibra solution for injection vials are for single-use only.

One 3 mL clear glass type 1 vial containing:

- 1 mL of Hemlibra solution (30 mg/mL) or
- 0,4 mL of Hemlibra solution (150 mg/mL) or
- 0,7 mL of Hemlibra solution (150 mg/mL) or
- 1 mL of Hemlibra solution (150 mg/mL).

Each pack of Hemlibra contains 1 glass vial.

Not all strengths may be marketed.

### What is needed for Hemlibra administration and is not contained in this pack

A syringe, a transfer needle with filter or a transfer needle or a vial adaptor and an injection needle are needed to withdraw Hemlibra solution from the vial and inject it subcutaneously.

### Holder of Certificate of Registration

Roche Products (Pty) Ltd

90 Bekker Road, Hertford Office Park,



Building E, Vorna Valley, Midrand,  
Johannesburg, 1686

South Africa

Roche Ethical Assistance Line (REAL) toll-free: 0800 21 21 25

**This leaflet was last revised on**

16 July 2024

**Registration number**

Hemlibra® 30 mg/1 mL: 53/30.1/0071

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Hemlibra® 105 mg/0,7 mL: 53/30.1/0073

Hemlibra® 150 mg/1 mL: 53/30.1/0074

**Instructions for Use**

**Hemlibra® Injection - Single-Dose Vial(s)**

**TRANSFER NEEDLE WITH FILTER**

**Option (for transfer of Hemlibra from vial to syringe)**

You must read, understand and follow the Instructions for Use before injecting Hemlibra. Your healthcare provider should show you how to prepare, measure, and inject Hemlibra properly before you use it for the first time. Ask your healthcare provider if you have any questions.

**Important Information:**

- **Do not** inject yourself or someone else unless you have been shown how to by your healthcare provider.
- Make sure the name Hemlibra is on on the box and vial label.
- Before opening the vial, read the vial label to make sure you have the correct medicine strength(s) needed to give the dose prescribed for you. You may need to use more than 1 vial to give yourself the correct dose.





- Check the expiry date on the box and vial label. **Do not** use if the expiry date has passed.
- **Only use the vial once.** After you inject your dose, throw away any unused Hemlibra left in the vial. Do not save unused medicine in the vial for later use.
- **Only use the syringes, transfer needles with filter, and injection needles that your healthcare provider prescribes.**
- **Use the syringes, transfer needles with filter and injection needles only once. Throw away any used syringes and needles.**
- If your prescribed dose is more than 2 mL, you will need to have more than one subcutaneous injection of Hemlibra; contact your healthcare provider for the injection instructions.
- You must inject Hemlibra only under the skin.

#### **Storing Hemlibra vials, needles and syringes:**

- Keep the vial in the original box to protect the medicine from light.
- Keep the vials, needles and syringes out of the sight and reach of children. Store the vial in the refrigerator.
- **Do not** freeze.
- **Do not** shake the vial.
- Take the vial out of the refrigerator 15 minutes before use and allow it to reach room temperature (below 30 °C) before preparing an injection.
- Once removed from the refrigerator, the unopened vial can be kept at room temperature for up to 7 days. After storage at room temperature unopened vials may be returned to the refrigerator. The total amount of time outside cold storage and at room temperature should not exceed 7 days.
- Discard vials that have been kept at room temperature for more than 7 days or have been in temperatures above 30 °C.
- Keep the transfer needle with filter, injection needle and syringe dry.

#### **Inspecting the medicine and your supplies**

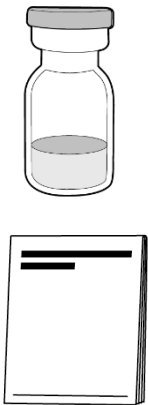
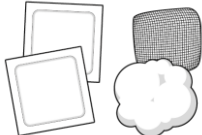
- Collect all supplies listed below to prepare and give your injection.
- **Check** the expiry date on the box, on the vial label and on the supplies listed below. **Do not use** if the expiry date has passed.

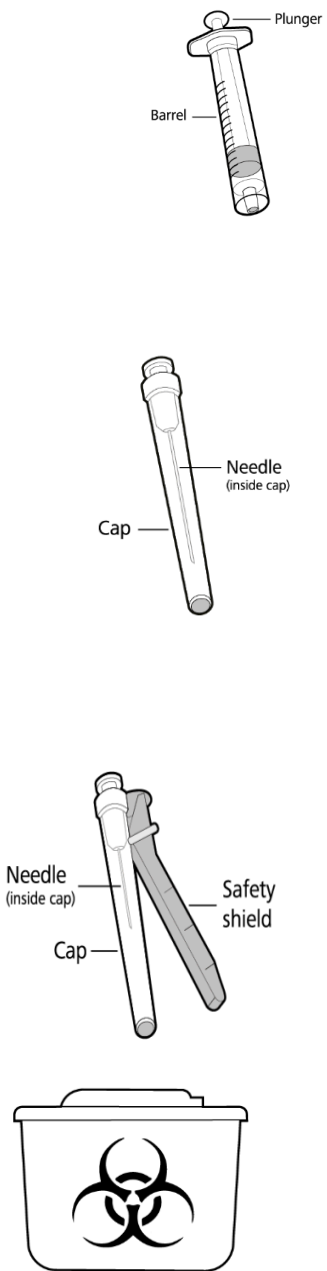
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**Do not use** the vial if:

- the medicine is cloudy, hazy or coloured.
- the medicine contains particles.
- the cap covering the stopper is missing.
- Inspect the supplies for damage. **Do not use** if they appear damaged or if they have been dropped.
- Place the supplies on a clean, well-lit flat work surface.

**INCLUDED IN THE BOX:**

	<ul style="list-style-type: none"><li>• <b>Vial containing the medicine</b></li> <li>• <b>Hemlibra Instructions for Use</b></li></ul>
<p><b>NOT INCLUDED IN THE BOX:</b></p> 	<ul style="list-style-type: none"><li>• <b>Alcohol wipes</b></li></ul> <p><b>Note:</b> If you need to use more than 1 vial to inject your prescribed dose, you must use a new alcohol wipe for each vial.</p> <ul style="list-style-type: none"><li>• <b>Gauze</b></li><li>• <b>Cotton Ball</b></li></ul>

	<ul style="list-style-type: none"><li>• <b>Syringe</b> <b>Note:</b> For injection amount up to 1 mL use a <b>1 mL syringe</b>. For injection amount between 1mL and 2 mL use a <b>2 mL or 3 mL syringe</b>.</li><li>• <b>18G Transfer Needle with 5 micrometer filter</b> <b>Note:</b> If you need to use more than 1 vial to inject your prescribed dose, you must use a new transfer needle with filter for each vial. <b>Do not</b> use the transfer needle with filter to inject medicine.</li><li>• <b>26G Injection Needle with safety shield</b> <b>Do not</b> use the injection needle to withdraw medicine from vial.</li></ul> <p><b>Sharps disposal container</b></p>
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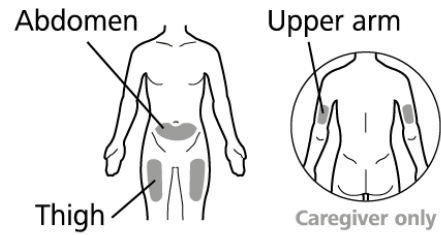
- Before use, allow the vial(s) to warm up to room temperature for about 15 minutes on a clean flat surface away from direct sunlight.
- Do not try to warm the vial by any other way.
- **Wash your hands** well with soap and water.



**Figure A**

### Selecting and preparing an injection site:

- Clean the chosen injection site area using an alcohol wipe.
- Let the skin dry for about 10 seconds. Do not touch, fan or blow on the cleaned area before your injection.



### For injection **you can use your:**

- Thigh (front and middle).
- Stomach area (abdomen), except for 5 cm around the navel (belly button).
- Outer area of the upper arm (only if a caregiver is giving the injection).
- You should use a different injection site for each injection, at least 2,5 cm away from the area you used for your previous injection.
- Do not inject into areas that could be irritated by a belt or waistband. Do not inject into moles, scars, bruises, or areas where the skin is tender, red, hard or the skin is broken.

**Figure B**

### Preparing the syringe for the injection

- Do not touch exposed needles or place them on a surface once the cap has been removed.
- Once the syringe has been filled with the medicine, the injection must be given immediately.



- Once the injection needle cap has been removed, the medicine in the syringe must be injected under the skin within 5 minutes. Do not use the syringe if the needle touches any surface.
- **Throw away any used vial(s), needles, vial or injection needle caps and used syringes in a sharps or puncture-proof container.**

#### **Important information after the injection**

- Do not rub the injection site after injection.
- **If you see drops of blood at the injection site, you can press a sterile cotton ball or gauze over the injection site for at least 10 seconds, until bleeding has stopped.**
- If you have bruising (small area of bleeding under the skin), an ice pack can also be pressed gently on the site. If bleeding does not stop, please contact your healthcare provider.

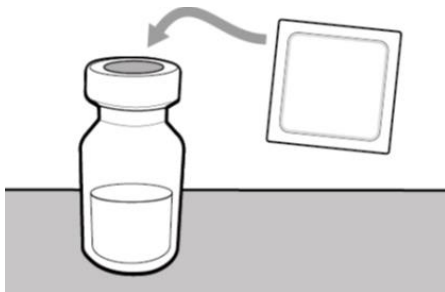
#### **Disposing of the medicine and supplies:**

##### **Important: Always keep the sharps disposal container out of reach of children.**

- Put your used needles and syringes in a sharps disposal container straight away after use. Do not throw away any loose needles and syringes in your household waste.
- If you do not have a sharps disposal container, you may use a household container that is:
  - made of heavy-duty plastic.
  - can be closed with a tight-fitting, puncture resistant lid, without sharps being able to come out.
  - upright and stable during use.
  - leak-resistant.
  - properly labelled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your local guidelines for the right way to dispose of your sharps disposal container.
- Do not throw away any used sharps disposal container in your household waste unless your local guidelines permit this. Do not recycle your used sharps disposal container.

## 1. PREPARATION

### Step 1. Remove vial cap and clean top

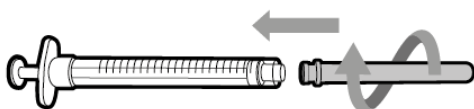


- Take the cap off the vial(s).
- Throw away the vial cap(s) into the sharps disposal container.

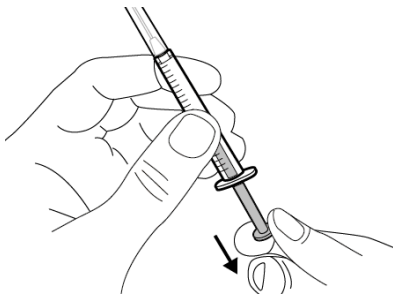
- Clean the top of the vial(s) stopper with an alcohol wipe.

- **Push and twist the transfer needle with filter clockwise** on to the syringe until it is fully attached.

### Step 2. Attach transfer needle with filter to syringe

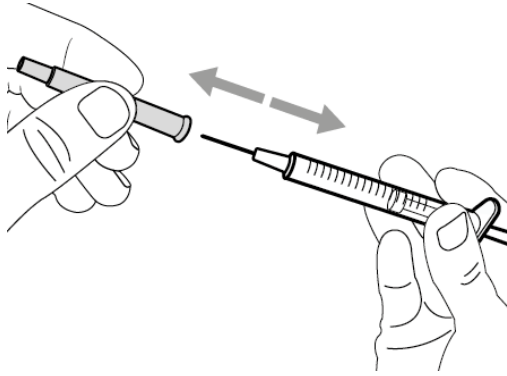


**Push and twist**

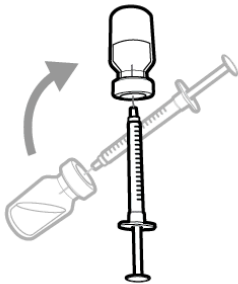
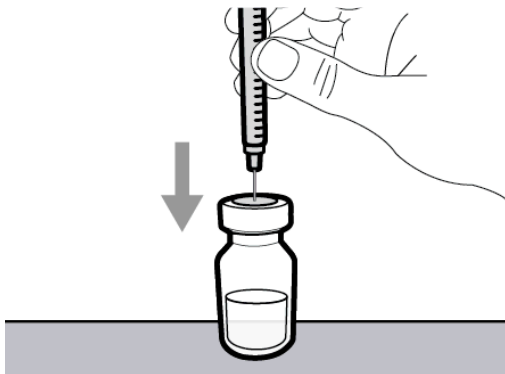


- Slowly pull back on the plunger and draw air into the syringe that is the same amount as your prescribed dose.

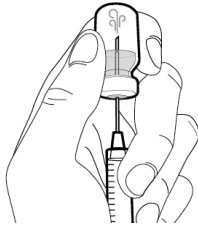
### Step 3. Uncap transfer needle with filter



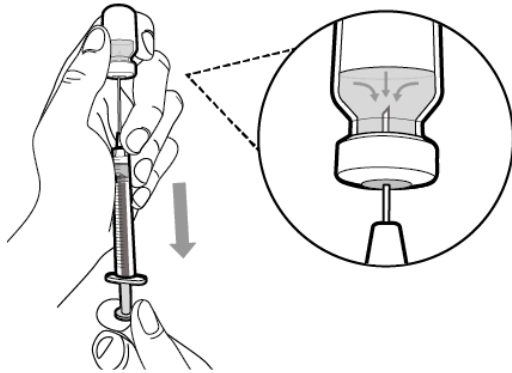
### Step 4. Inject air into vial



- Hold the syringe by the barrel with the transfer needle with filter pointing up.
- Carefully pull the transfer needle with filter cap straight off and away from your body. **Do not throw the cap away. Place the transfer needle with filter cap down on a clean flat surface.** You will need to recap the transfer needle with filter after transferring the medicine.
- **Do not touch** the needle tip or place it on a surface after the needle cap has been removed.
- Keep the vial on the flat working surface and insert the transfer needle with filter and syringe straight down into the centre of the vial stopper.
- Keep the needle in the vial and turn the vial upside down.



### Step 5. Transfer medicine to syringe



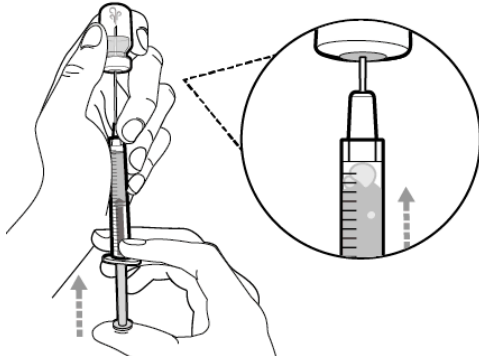
- With the needle pointing upwards, push on the plunger to inject the air from the syringe **above the medicine**.
  - Keep your finger pressed down on the syringe plunger.
  - **Do not** inject air into the medicine as this could create air bubbles or foam in the medicine.
  - Slide the tip of the needle down so that it is **within the medicine**.
  - **Slowly** pull back the plunger to prevent air bubbles/foam.
- Fill the syringe with more than the amount of medicine needed for your prescribed dose.
- Be careful not to pull the plunger out of the syringe.

**Important:** If your prescribed dose is more than the amount of medicine in the vial, **withdraw all of the medicine** and go to the “**Combining Vials**” section now.

### Step 6. Remove air bubbles

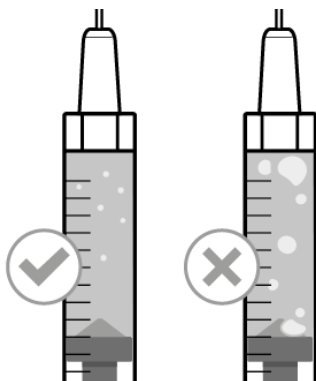
- Keep the needle in the vial and check the syringe for larger air bubbles. Large air bubble can reduce the dose you receive.
- **Remove the larger air bubbles** by gently **tapping** the syringe barrel with your





fingers until the air bubbles rise to the top of the syringe. Move the tip of the needle **above the medicine** and slowly push the plunger up to push the air bubbles out of the syringe

- If the amount of medicine in the syringe is now at or below your prescribed dose, move the tip of the needle to **within the medicine** and slowly **pull** back the plunger until you have **more** than the amount of medicine needed for your **prescribed dose**.
- Be careful not to pull the plunger out of the syringe.
- Repeat the steps above until you have removed the larger air bubbles.



**Note:** Ensure you have enough medicine in the syringe to complete your dose before moving onto the next step. If you cannot remove all medicine, turn the vial upright to reach the remaining amount.



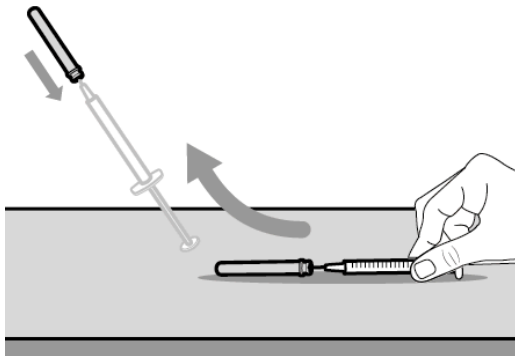
**Do not** use the transfer needle with filter to inject medicine as this may cause pain and

bleeding.

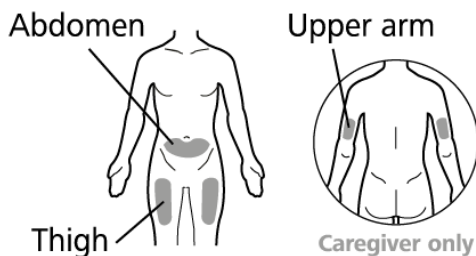
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## 2. INJECTION

### Step 7. Recap transfer needle with filter



4. Remove the syringe and transfer needle with filter from the vial.
5. **Using one hand, slide** the transfer needle with filter into the cap and **scoop upwards** to cover the needle.
6. Once the needle is covered, push the transfer needle with filter cap towards the syringe to fully attach it with **one hand** to prevent accidentally hurting yourself with the needle.

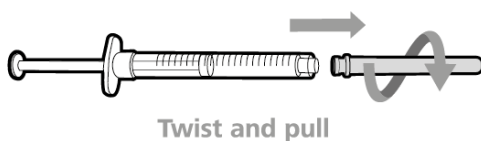


- Select and **clean** your injection site with an alcohol wipe.

### Step 8. Clean injection site

---

### Step 9. Remove transfer needle with filter

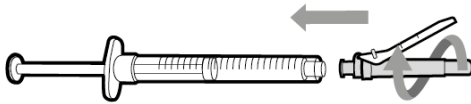


- Remove the transfer needle with filter from the syringe by twisting anticlockwise and gently pulling.
- Throw away the used transfer needle with filter into a sharps disposal container.

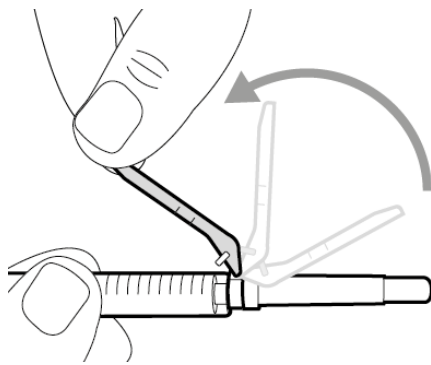
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**Step 10. Attach injection needle to syringe**

- Push and twist the injection needle clockwise onto the syringe until it is fully attached.



Push and twist

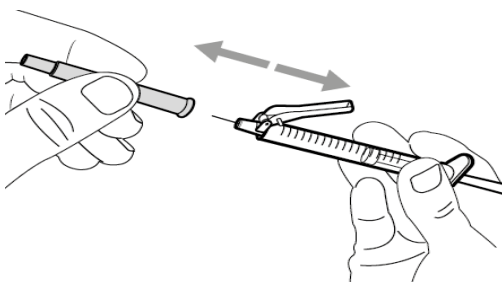


**Step 11.**  
**Move safety shield**

- Move the safety shield away from the needle and **towards** the syringe barrel.

---

**Step 12. Uncap injection needle**

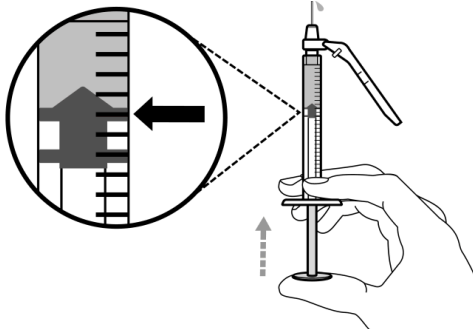


- **Carefully** pull the injection needle cap straightaway from the syringe.
- Throw away the cap into a sharps disposal container.
- **Do not touch** the needle tip or allow it to touch any surface.
- After the injection needle cap has been removed, the medicine in the syringe must be injected within 5 minutes.

---

### Step 13. Adjust plunger to prescribed

dose

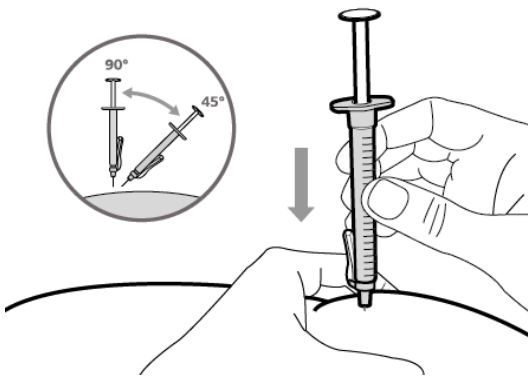


- Hold the syringe with the needle pointing up and slowly push the plunger to your prescribed dose.
- **Check your dose**, ensure the top rim of the plunger is in line with the mark on the syringe for your prescribed dose.

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### Step 14. Subcutaneous (under the skin)

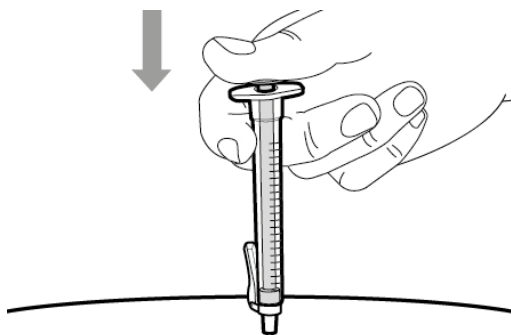
Injection



- Pinch the selected injection site and fully insert the needle at a **45° to 90° angle** with a quick, firm action. **Do not** hold or push on the plunger while inserting the needle.
- Hold the position of the syringe and let go of the pinched injection site.

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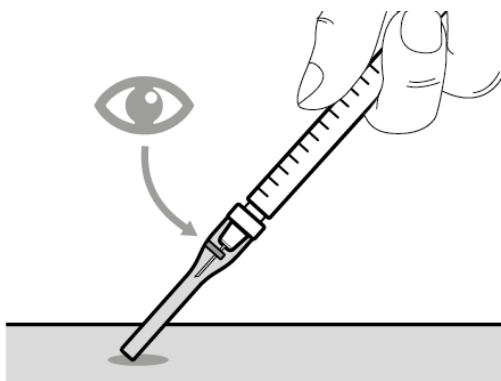
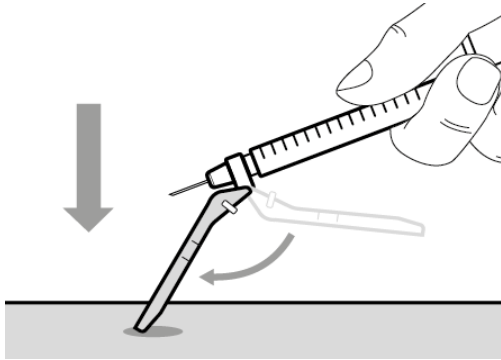
### Step 15. Inject the medicine



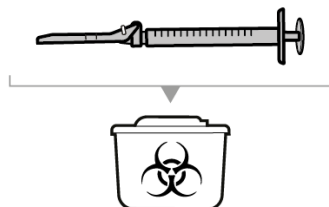
- Slowly inject all of the medicine by gently pushing the plunger all the way down.
- Remove the needle and syringe from the injection site at the same angle as inserted.

### 3. DISPOSAL

#### Step 16. Cover needle with safety shield



#### Step 17. Throw away the syringe and needle.



- Move the safety shield forward 90°, away from the syringe barrel.
- Holding the syringe with one hand, **press the safety shield down** against a flat surface with a firm, quick motion until you hear a “click”.
- If you do not hear a click, look to see that the needle is fully covered by the safety shield.
- Keep your fingers behind the safety shield and away from the needle at all times.
- **Do not** detach injection needle
- Put **your** used needles and syringes in a sharps disposal container right away after use. For further information refer to the section “Disposing of the medicine and supplies”.
- **Do not** try to remove the used injection needle from the used syringe.
- **Do not recap** the injection needle with the cap.
- **Important:** Always keep the sharps disposal

container out of reach of children.

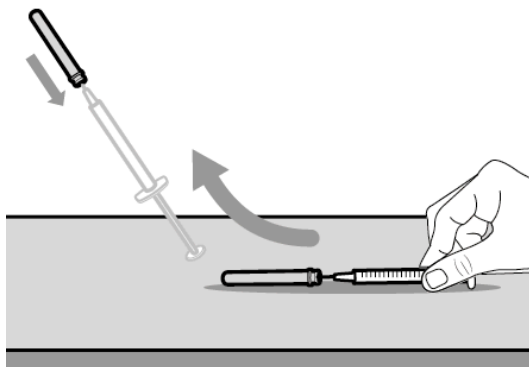
- Throw away any used caps, vial(s), needles and syringes in a sharps or puncture-proof container.

### Combining Vials

If you need to use more than 1 vial to get to your prescribed dose, follow these steps after you have drawn up the medicine from the first vial:

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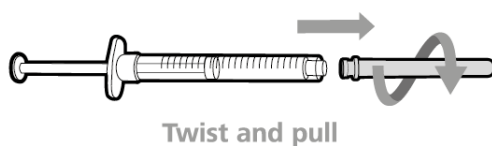
#### Step A. Recap transfer needle with filter



- Remove the syringe and transfer needle with filter from the first vial.
- **Using one hand**, slide the transfer needle with filter into the cap and **scoop upwards** to cover the needle.
- Once the needle is covered, push the transfer needle with filter cap toward the syringe to fully attach it with **one hand** to prevent accidentally injuring yourself with the needle.

---

#### Step B. Remove transfer needle with filter



- Remove the transfer needle with filter from the syringe by twisting anticlockwise and gently pulling.
- Throw away the used transfer needle with filter into a sharps disposal container.

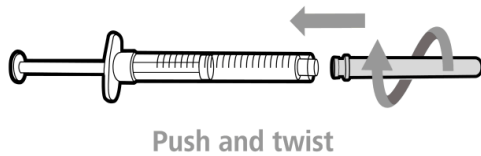
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#### Step C. Attach a new transfer needle

**Note: You must use a new transfer needle with**

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**with filter to syringe**

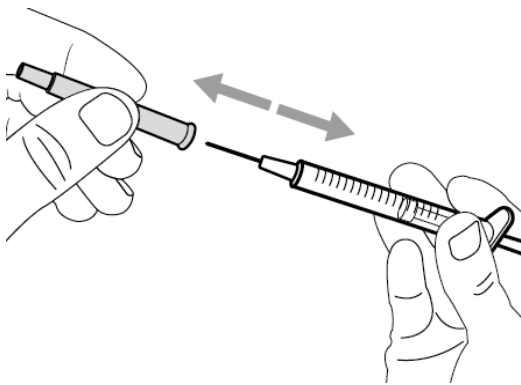


**filter each time you withdraw medicine from a new vial.**

- Push and twist a **new** transfer needle with filter clockwise on to the syringe until it is fully attached.
- Slowly pull back the plunger and draw some air into the syringe.

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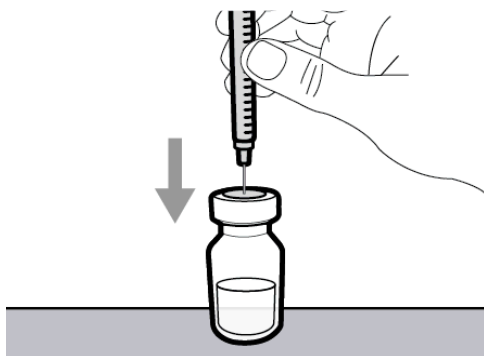
**Step D. Uncap transfer needle with filter**



- Hold the syringe by the barrel with the transfer needle cap pointing up.
- Carefully pull the transfer needle with filter cap straight off and away from your body. **Do not throw the cap** away. You will need to recap the transfer needle with filter after drawing up the medicine.
- **Do not touch** the needle tip.

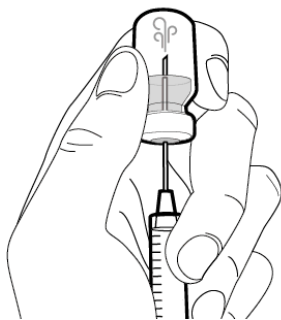
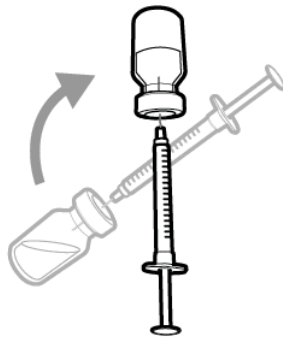
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**Step E. Inject air into vial**



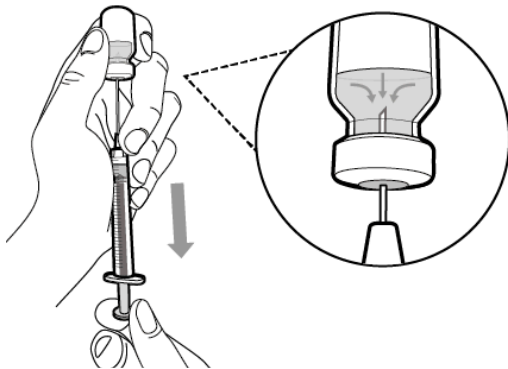
- With the new vial on the flat working surface, insert the new transfer needle with filter and syringe, straight down into the **centre** of the vial stopper.

- Keep the transfer needle with filter in the vial and turn the vial upside down.



- With the needle pointing upwards, inject the air from the syringe **above the medicine**.
- Keep your finger pressed down on the syringe plunger.
- **Do not** inject air into the medicine as this could create air bubbles or foam in the medicine.

#### Step F. Transfer medicine to syringe



- Slide the tip of the needle down so that it is **within the medicine**.
- **Slowly** pull back the plunger to prevent air bubbles/foam.
- Fill the syringe barrel more than the amount of medicine needed for your prescribed dose.
- Be careful not to pull the plunger out of the syringe.

**Note:** Ensure you have enough medicine in the syringe to complete your dose before moving onto the next steps. If you cannot remove all of the medicine, turn the vial upright to reach the remaining amount.





**Do not** use the transfer needle with filter to inject medicine as this may cause harm such as pain and bleeding.

---

**Repeat steps A to F with each additional vial until you have more than your prescribed dose. Once completed, keep the transfer needle with filter inserted in the vial and return to Step 6. Continue with the remaining steps.**

### **Instructions for Use**

#### **Hemlibra® Injection - Single-Dose Vial(s)**

#### **TRANSFER NEEDLE**

#### **Option (for transfer of Hemlibra from vial to syringe)**

You must read, understand and follow the Instructions for Use before injecting Hemlibra. Your healthcare professional should show you how to prepare, measure, and inject Hemlibra properly before you use it for the first time. Ask your healthcare professional if you have any questions.

#### **Important Information:**

- **Do not** inject yourself or someone else unless you have been shown how to by your healthcare professional.
- Make sure the name Hemlibra appears on the box and vial label.
- Before opening the vial, read the vial label to make sure you have the correct medicine strength(s) needed to give the dose prescribed by your healthcare professional. Depending on your dose, you may need to use more than 1 vial to give yourself the correct dose.
- Check the expiration date on the box and vial label. Do not use if the expiration date has passed.



- **Only use the vial once.** After you inject your dose, dispose of (throw away) any unused Hemlibra left in the vial. Do not save unused medicine in the vial for later use.
- **Only use the syringes, transfer needles, and injection needles that your healthcare professional prescribes.**
- **Use the syringes, transfer needles and injection needles only once. Dispose of (throw away) any used caps, vials, syringes and needles.**
- If your prescribed dose is more than 2 mL, you will need to have more than one (1) subcutaneous injection of Hemlibra; contact your healthcare provider for the appropriate injection instructions.
- You must inject Hemlibra only under the skin.

#### **Storing Hemlibra vials, needles and syringes:**

- Keep the vial in the original box to protect the medicine from light.
- Keep the vials, needles and syringes out of the sight and reach of children. Store the vial in the refrigerator.
- Do not freeze.
- Do not shake the vial.
- Take the vial out of the refrigerator 15 minutes before use and allow it to reach room temperature before preparing an injection.
- Once removed from the refrigerator, the unopened vial can be kept at room temperature (below 30 °C) for up to 7 days. After storage at room temperature unopened vials may be returned to the refrigerator. The total amount of time outside of the refrigerator and at room temperature should not exceed 7 days.
- Discard vials that have been kept at room temperature for more than 7 days or have been in temperatures above 30 °C.
- Keep the transfer needle, injection needle and syringe dry.

#### **Inspecting the medicine and your supplies**

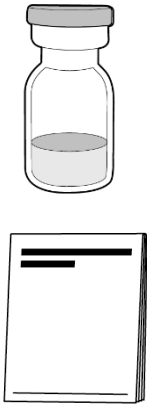
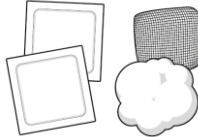
- Collect all supplies listed below to prepare and give your injection.

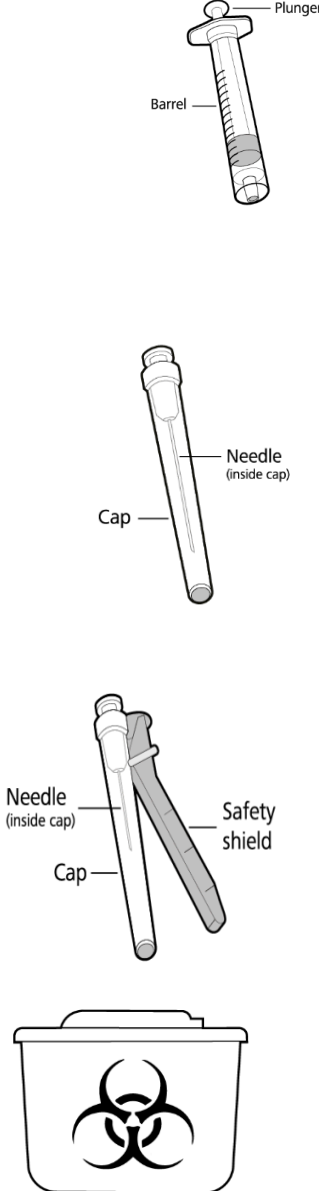
- Check the expiry date on the box, on the vial label and on the supplies listed below. Do not use if the expiry date has passed.

**Do not use the vial if:**

- the medicine is cloudy, hazy or coloured.
- the medicine contains particles.
- the cap covering the stopper is missing.
- Inspect the supplies for damage. Do not use if they appear damaged or if they have been dropped.
- Place the supplies on a clean, well-lit flat work surface.

**INCLUDED IN THE BOX:**

	<ul style="list-style-type: none"><li>• Vial containing the medicine</li><li>• Hemlibra instructions for Use</li></ul>
<p><b>NOT INCLUDED IN THE BOX:</b></p> 	<ul style="list-style-type: none"><li>• <b>Alcohol wipes</b></li></ul> <p><b>Note:</b> If you need to use more than 1 vial to inject your prescribed dose, you must use a new alcohol wipe for each vial.</p> <ul style="list-style-type: none"><li>• <b>Gauze</b></li><li>• <b>Cotton Ball</b></li></ul>

	<ul style="list-style-type: none"><li>• <b>Syringe</b></li></ul> <p><b>Note:</b> For injection amount up to 1 mL use a 1 mL syringe.</p> <p>For injection amount between 1mL and 2 mL use a 2 or 3 mL syringe.</p> <ul style="list-style-type: none"><li>• <b>18G Transfer Needle</b></li></ul> <p><b>Note:</b> If you need to use more than 1 vial to inject your prescribed dose, you must use a new transfer needle for each vial.</p> <p>Do not use the transfer needle to inject medicine.</p> <ul style="list-style-type: none"><li>• <b>26G Injection Needle with safety shield</b></li></ul> <p>Do not use the injection needle to withdraw medicine from vial.</p> <p>Sharps disposal container</p>
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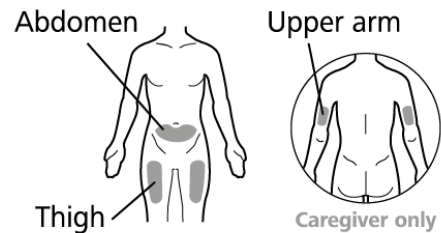
**Figure A**

- Before use, allow the vial(s) to warm up to room temperature for about 15 minutes on a clean flat surface away from direct sunlight.
- Do not try to warm the vial by any other way.
- Wash your hands well with soap and water.



### Selecting and preparing an injection site:

- Clean the chosen injection site area using an alcohol wipe.
- Let the skin dry for about 10 seconds. Do not touch, fan or blow on the cleaned area before your injection.



### For injection you can use your:

- Thigh (front and middle).
- Stomach area (abdomen), except for 5 cm around the navel (belly button).
- Outer area of the upper arm (only if a caregiver is giving the injection).
- You should use a different injection site each time you give an injection, at least 2,5 cm away from the area you used for your previous injection.
- Do not inject into areas that could be irritated by a belt or waistband. Do not inject into moles, scars, bruises, or areas where the skin is tender, red, hard or the skin is broken.

### Preparing the syringe for the injection

- Do not touch exposed needles or place them on a surface once the cap has been removed.
- Once the syringe has been filled with the medicine, it must be used immediately.
- Once the injection needle cap has been removed, the medicine in the syringe must be injected under the skin within 5 minutes. Do not use the syringe if the needle touches any surface.

### **Important information after the injection**

- Do not rub the injection site after an injection.
- If you see drops of blood at the injection site, you can press a sterile cotton ball or gauze over the injection site for at least 10 seconds, until bleeding has stopped.
- If you have bruising (small area of bleeding under the skin), an ice pack can also be applied with gentle pressure to the site. If bleeding does not stop, please contact your healthcare provider.

### **Disposing of the medicine and supplies:**

#### **Important: Always keep the sharps disposal container out of reach of children.**

- Throw away any used vial(s), needles, vial/injection needle caps and used syringes in a sharps/puncture-proof container.
- Put your used needles and syringes in a sharps disposal container straight away after use. Do not dispose of (throw away) any loose needles and syringes in your household waste.
- If you do not have a sharps disposal container, you may use a household container that is:
  - made of heavy-duty plastic.
  - can be closed with a tight-fitting, puncture resistant lid, without sharps being able to come out.
  - upright and stable during use.
  - leak-resistant.
  - properly labelled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your local guidelines for the right way to dispose of (throw away) your sharps disposal container.
- Do not dispose of (throw away) any used sharps disposal container in your household waste unless your local guidelines permit this. Do not recycle your used sharps disposal container.

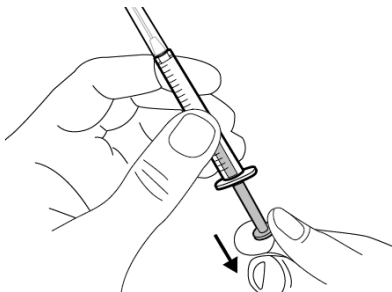
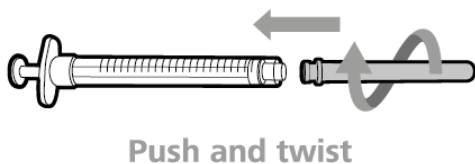
## 1. PREPARATION

### Step 1. Remove vial cap and clean top



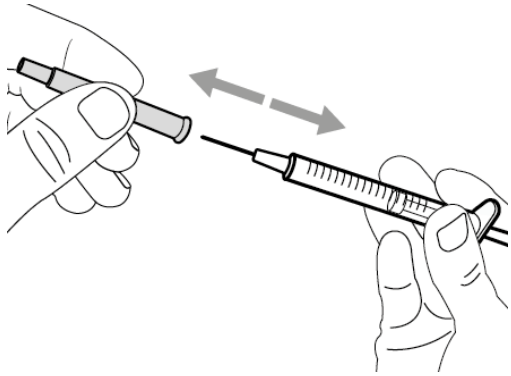
- Take the cap off the vial(s).
- Clean the top of the vial(s) stopper with an alcohol wipe.
- Dispose of (throw away) the vial cap(s) into the sharps disposal container.
- **Push and twist the transfer needle clockwise** on to the syringe until it is fully attached.
- Slowly pull back on the plunger and draw air into the syringe that is the same amount for your prescribed dose.

### Step 2. Attach transfer needle to syringe

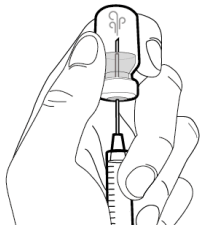
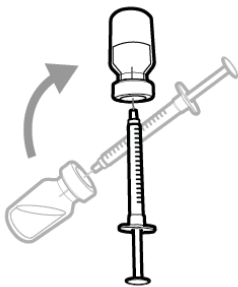
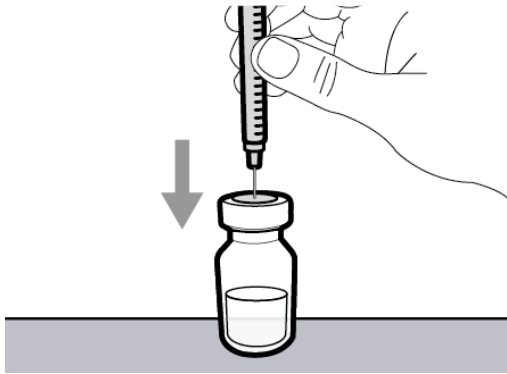


### Step 3. Uncap transfer needle

- Hold the syringe by the barrel with the transfer needle pointing up.
- Carefully pull the transfer needle cap straight off and away from your body. **Do**



#### Step 4. Inject air into vial

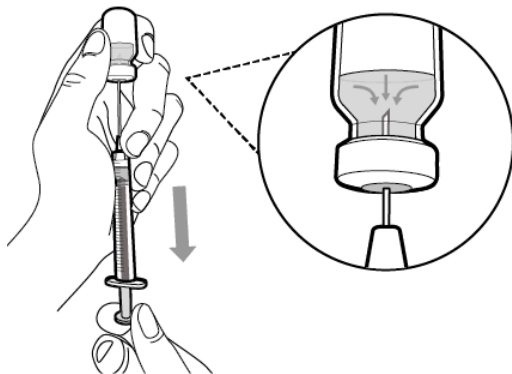


**not throw the cap away. Place the transfer needle cap down on a flat surface.** You will need to recap the transfer needle after transferring the medicine.

- **Do not touch** the needle tip or place it on a surface after the needle cap has been removed.
- Keep the vial on the flat working surface and insert the transfer needle and syringe straight down into the centre of the vial stopper.
- Keep the needle in the vial and turn the vial upside down.
- With the needle pointing upwards, push on the plunger to inject the air from the syringe **above the medicine**.
- Keep your finger pressed down on the syringe plunger.
- **Do not** inject air into the medicine as this could create air bubbles in the medicine.



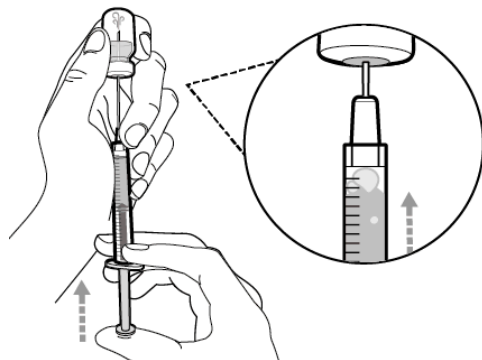
### Step 5. Transfer medicine to syringe



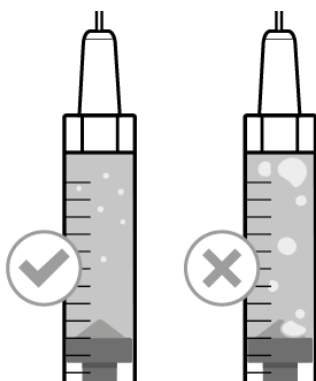
- Slide the tip of the needle down so that it is within the medicine.
- Slowly pull back the plunger to fill the syringe with more than the amount of medicine needed for your prescribed dose.
- Be careful not to pull the plunger out of the syringe.

**Important:** If your prescribed dose is more than the amount of medicine in the vial, **withdraw all of the medicine** and go to the **Combining Vials** section now.

### Step 6. Remove air bubbles



- Keep the needle in the vial and check the syringe for larger air bubbles. Too large an air bubble can reduce the dose you receive.
- **Remove the larger air bubbles** by gently tapping the syringe barrel with your fingers until the air bubbles rise to the top of the syringe. Move the tip of the needle **above the medicine** and slowly push the plunger up to push the air bubbles out of the syringe
- If the amount of medicine in the syringe is now at or below your prescribed dose, move the tip of the needle to **within the medicine** and slowly **pull** back the plunger



until you have **more** than the amount of medicine needed for your **prescribed dose**.

- Be careful not to pull the plunger out of the syringe
- Repeat the steps above until you have removed the larger air bubbles.

**Note:** Ensure you have enough medicine in the syringe to complete your dose before moving onto the next step. If you cannot remove all of the medicine, turn the vial upright to reach the remaining amount.

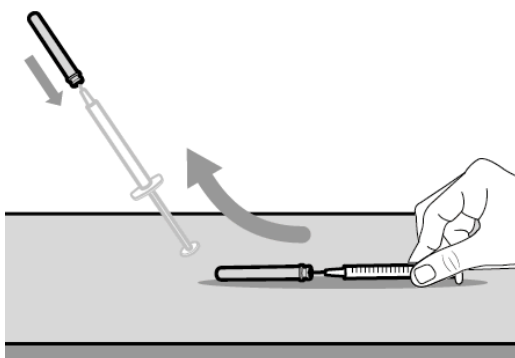


**Do not** use the transfer needle to inject medicine as this may cause harm such as pain and bleeding.

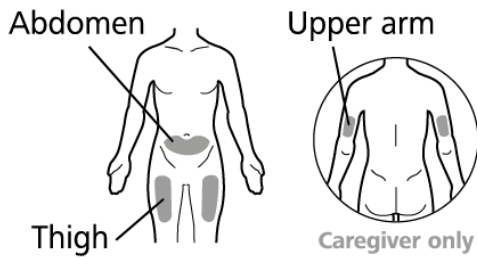
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## 2. INJECTION

### Step 7. Recap transfer needle



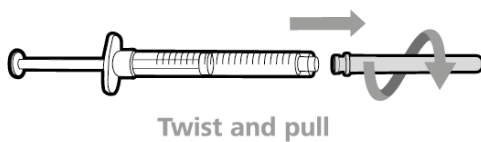
3. Remove the syringe and transfer needle from the vial.
4. **Using one hand, slide** the transfer needle into the cap and **scoop upwards** to cover the needle.
5. Once the needle is covered, push the transfer needle cap towards the syringe to fully attach it with **one hand** to prevent accidentally hurting yourself with the needle



- Select and clean your injection site with an alcohol wipe.

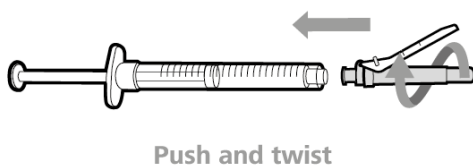
### Step 8. Clean injection site

### Step 9. Remove transfer needle



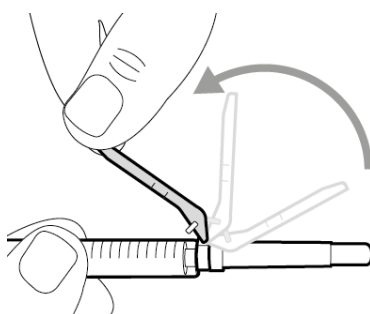
- Remove the transfer needle from the syringe by twisting anticlockwise and gently pulling.
- Dispose of (throw away) the used transfer needle into a sharps disposal container.

### Step 10. Attach injection needle to syringe



- Push and twist the injection needle clockwise onto the syringe until it is fully attached.

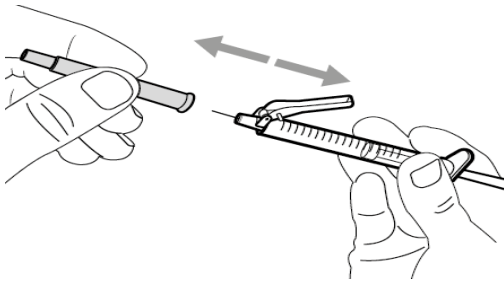
### Step 11. Move safety shield



- Move the safety shield away from the needle and **towards** the syringe barrel.

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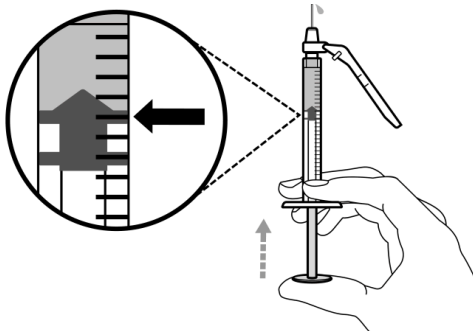
### Step 12. Uncap injection needle



- Carefully pull the injection needle cap straightaway from the syringe.
- Dispose of (throw away) the cap into a sharps disposal container
- **Do not touch** the needle tip or allow it to touch any surface.
- After the injection needle cap has been removed, the medicine in the syringe must be injected within 5 minutes.

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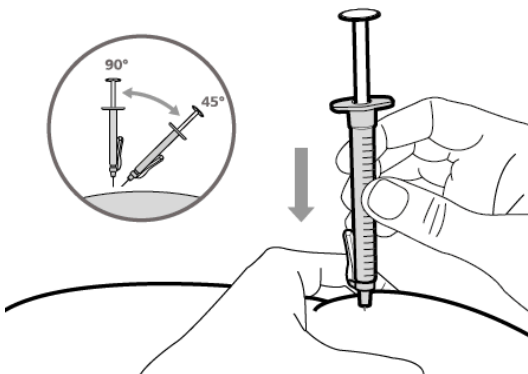
### Step 13. Adjust plunger to prescribed dose



- Hold the syringe with the needle pointing up and slowly push the plunger to your prescribed dose.
- **Check your dose**, ensure the top rim of the plunger is in line with the mark on the syringe for your prescribed dose.

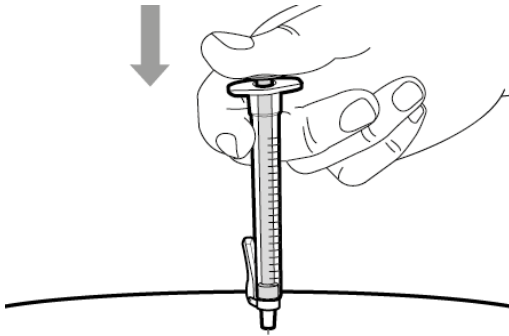
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### Step 14. Subcutaneous (under the skin) Injection



- Pinch the selected injection site and fully insert the needle at a **45° to 90° angle** with a quick, firm action. **Do not** hold or push on the plunger while inserting the needle.
- Hold the position of the syringe and let go of the pinched injection site.

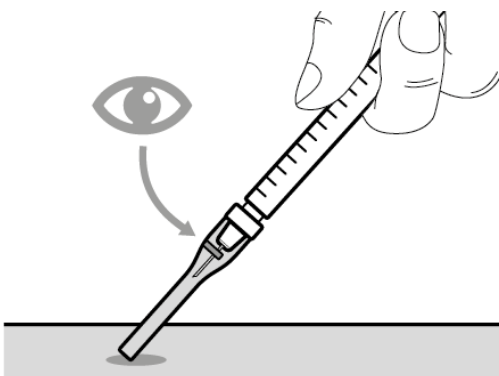
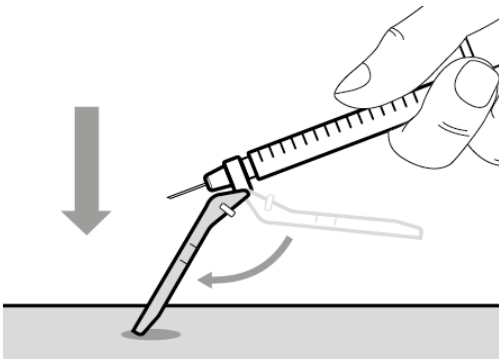
### Step 15. Inject the medicine



- Slowly inject all of the medicine by gently pushing the plunger all the way down.
- Remove the needle and syringe from the injection site at the same angle as inserted.

## 3. DISPOSAL

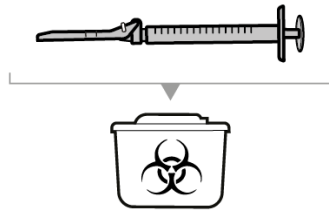
### Step 16. Cover needle with safety shield



- Move the safety shield forward 90°, away from the syringe barrel.
- Holding the syringe with one hand, **press the safety shield down** against a flat surface with a firm, quick motion until you hear a “click”.
- If you do not hear a click, look to see that the needle is fully covered by the safety shield.
- Keep your fingers behind the safety shield and away from the needle at all times.
- **Do not** detach injection needle

### Step 17. Dispose of (throw away) the syringe and needle.

- Put your used needles and syringes in a sharps disposal container right away after



use. For further information refer to the section “Disposing of the medicine and supplies”.

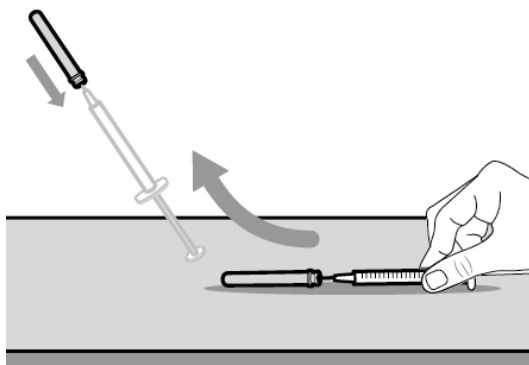
- Do not try to remove the used injection needle from the used syringe.
- Do not recap the injection needle with the cap.
- Important: Always keep the sharps disposal container out of reach of children.
- Throw away any used caps, vial(s), needles and syringes in a sharps or puncture-proof container.

### Combining Vials

If you need to use more than 1 vial to get to your total prescribed dose, follow these steps after you have drawn up the medicine from the first vial:

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#### Step A. Recap transfer needle



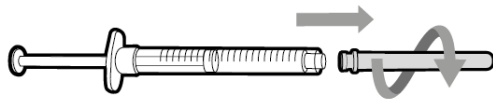
- Remove the syringe and transfer needle from the first vial.
- **Using one hand**, slide the transfer needle into the cap and **scoop upwards** to cover the needle.
- Once the needle is covered, push the transfer needle cap toward the syringe to fully attach it with one hand to prevent accidentally injuring yourself with the needle.

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#### Step B. Remove transfer needle

- Remove the transfer needle from the syringe by

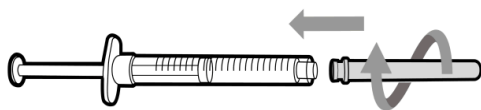
twisting anticlockwise and gently pulling.



Twist and pull

- Dispose of (throw away) the used transfer needle into a sharps disposal container.

### Step C. Attach a new transfer needle to Syringe

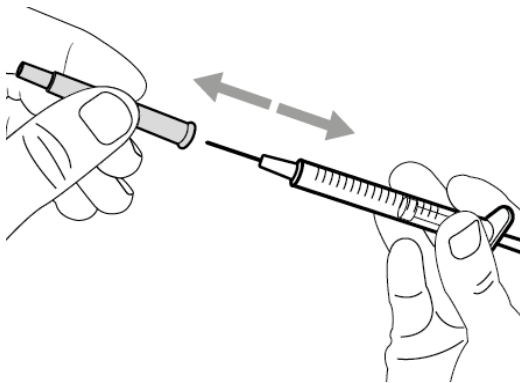


Push and twist

**Note: You must use a new transfer needle each time you withdraw medicine from a new vial.**

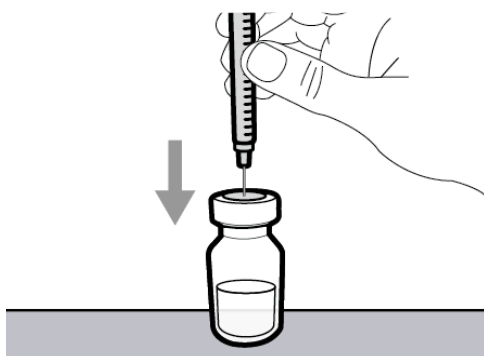
- Push and twist a **new** transfer needle clockwise on to the syringe until it is fully attached.
- Slowly pull back the plunger and draw some air into the syringe.

### Step D. Uncap transfer needle



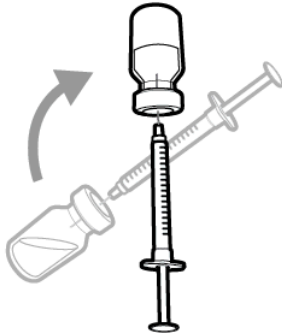
- Hold the syringe by the barrel with the transfer needle cap pointing up.
- Carefully pull the transfer needle cap straight off and away from your body. Do not throw the cap away. You will need to recap the transfer needle after drawing up the medicine.
- Do not touch the needle tip.

### Step E. Inject air into vial

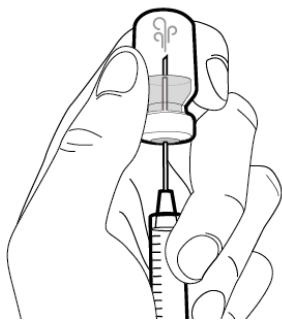


- With the new vial on the flat working surface, insert the new transfer needle and syringe, straight down into the centre of the vial stopper.

- Keep the transfer needle in the vial and turn the vial upside down.

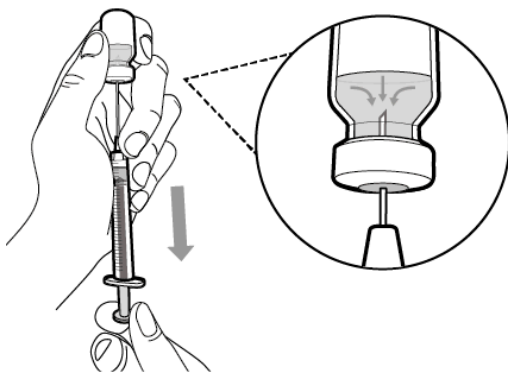


- With the needle pointing upwards, inject the air from the syringe **above the medicine**.
- Keep your finger pressed down on the syringe plunger.
- Do not inject air into the medicine as this could create air bubbles in the medicine.



#### Step F. Transfer medicine to syringe

- Slide the tip of the needle down so that it is **within the medicine**.
- Slowly pull back the plunger to fill the syringe barrel more than the amount of medicine needed for your prescribed dose.
- Be careful not to pull the plunger out of the syringe.



**Note:** Ensure you have enough medicine in the syringe to complete your dose before moving onto the next step. If you cannot remove all of the medicine, turn the vial upright to reach the remaining amount.





Do not use the transfer needle to inject medicine as this may cause harm such as pain and bleeding.

**Repeat steps A to F with each additional vial until you have more than your prescribed dose. Once completed, keep the transfer needle inserted in the vial and return to Step 6. Continue with the remaining steps.**

### Instructions for Use

#### Hemlibra® Injection - Single-Dose Vial(s)

#### VIAL ADAPTOR

Option (for transfer of Hemlibra from vial to syringe)

You must read, understand and follow the Instructions for Use before injecting Hemlibra. Your healthcare provider should show you how to prepare, measure, and inject Hemlibra properly before you use it for the first time. Ask your healthcare provider if you have any questions.

#### Important Information:

Do not use these instructions when using a transfer needle to withdraw Hemlibra from vial. These instructions are for use with the Vial Adaptor only.

- **Do not** inject yourself or someone else unless you have been shown how to by your healthcare provider.
- Make sure the name Hemlibra is on the box and vial label.
- Before opening the vial, read the vial label to make sure you have the correct medicine strength(s) to give the dose prescribed for you. You may need to use more than 1 vial to give yourself the correct dose.



- Check the expiry date on the box and vial label. **Do not** use if the expiry date has passed.
- **Only use the vial once.** After you inject your dose, throw away any unused Hemlibra left in the vial. **Do not** save unused medicine in the vial for later use.
- **Only use the syringes, vial adaptors, and injection needles that your healthcare provider prescribes.**
- **Use the syringes, vial adaptors and injection needles only once. Throw away any used caps, vial(s) and syringes and needles.**
- If your prescribed dose is more than 2 mL, you will need to have more than one subcutaneous injection of Hemlibra; contact your healthcare provider for the injection instructions.
- You must inject Hemlibra only under the skin

**Storing Hemlibra vials, vial adaptors, needles and syringes:**

- Keep the vial in the original box to protect the medicine from light.
- Keep vials, vial adaptors, needles and syringes out of the sight and reach of children. Store the vial in the refrigerator.
- **Do not** freeze.
- **Do not** shake the vial.
- Take the vial out of the refrigerator 15 minutes before use and allow it to reach room temperature (below 30 °C) before preparing an injection.



Once removed from the refrigerator, the unopened vial can be kept at room temperature for up to 7 days. After storage at room temperature unopened vials may be returned to the refrigerator. The total amount of time outside cold storage and at room temperature should not exceed 7 days.

- Discard vials that have been kept at room temperature for more than 7 days or have been in temperatures above 30 °C.
- Keep the vial adaptor, injection needle and syringe dry.

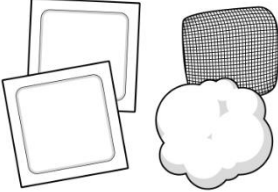


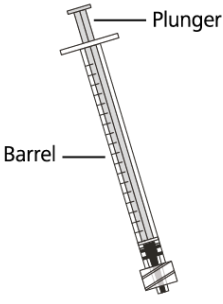
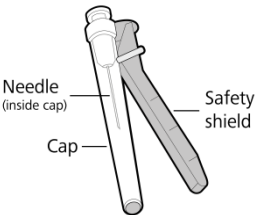
**Inspecting the medicine and your supplies:**


- Collect all supplies listed below to prepare and give your injection.
- **Check** the expiry date on the box, on the vial label, and on the supplies listed below. **Do not use** if the expiry date has passed.
- **Do not use** the vial if:
  - the medicine is cloudy, hazy or coloured.
  - the medicine contains particles.
  - the cap covering the stopper is missing.
- Inspect the supplies for damage. **Do not use** if they appear damaged or if they have been dropped.
- **Place the supplies on a clean, well-lit flat work surface.**

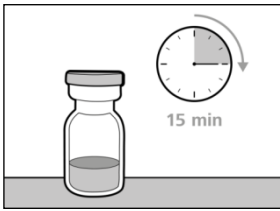
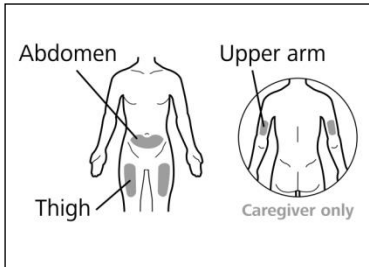
**INCLUDED IN THE BOX:**

	<ul style="list-style-type: none"><li>● <b>Vial containing the medicine</b></li></ul>
	<ul style="list-style-type: none"><li>● <b>Hemlibra Instructions for Use</b></li></ul>

**NOT INCLUDED IN THE BOX:**

	<ul style="list-style-type: none"> <li>● <b>Alcohol wipes</b></li> </ul> <p><b>Note:</b> If you need to use more than 1 vial to inject your prescribed dose, you must use a new alcohol wipe for each vial.</p> <ul style="list-style-type: none"> <li>● <b>Gauze</b></li> <li>● <b>Cotton ball</b></li> </ul>
	<ul style="list-style-type: none"> <li>● <b>Vial adaptor</b> (To be added on top of vial).</li> </ul> <p><b>Note:</b> Used for withdrawing medicine from the vial to the syringe. If you need to use more than 1 vial to inject your prescribed dose, you must use a new vial adaptor for each vial.</p> <p> <b>Do not insert injection needle into vial adaptor.</b></p>
	<ul style="list-style-type: none"> <li>● Syringe with Low Dead Space (LDS) Plunger</li> </ul> <p>Important:</p> <ul style="list-style-type: none"> <li>○ For injection amount up to 1 mL use a 1 mL LDS syringe.</li> <li>○ For injection amount over 1 mL use 3 mL LDS syringe.</li> </ul> <p><b>Note:</b> Do not use 3 mL LDS syringe for doses up to 1 mL.</p>
	<ul style="list-style-type: none"> <li>● <b>Injection needle with safety shield</b> (Used to inject medicine).</li> </ul> <p><b>Do not</b> insert the injection needle into vial adaptor or use the injection needle to withdraw medicine from vial.</p>

	<ul style="list-style-type: none"><li>● <b>Sharps disposal container</b></li></ul>
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<p><b>Get ready:</b></p> <ul style="list-style-type: none"><li>● Before use, allow the vial(s) to reach room temperature for about 15 minutes on a clean flat surface away from direct sunlight.</li><li>● <b>Do not</b> try to warm the vial by any other way.</li><li>● Wash your hands <b>well with soap and water</b>.</li></ul>	
<p><b>Selecting and preparing an injection site:</b></p> <ul style="list-style-type: none"><li>● Clean the chosen injection site area using an alcohol wipe.</li><li>● Let the skin dry for about 10 seconds. Do not touch, fan or blow on the cleaned area before your injection.</li></ul>	

**For your injection, you can use your:**

- Thigh (front and middle).
- Stomach area (abdomen), except for the 5 cm around the navel (belly button).
- Outer area of the upper arm (only if a caregiver is giving the injection).
- You should use a different injection site for each injection, at least 2,5 cm away from the area you used for your previous injection.
- Do not inject into areas that could be irritated by a belt or waistband. Do not inject into moles, scars, bruises, or areas where the skin is tender, red, hard or the skin is broken.



### **Preparing the syringe for injection:**

- Do not touch exposed needles or place them on a surface once the cap has been removed.
- Once the syringe has been filled with the medicine, the injection must be given immediately.
- Once the injection needle cap has been removed, the medicine in the syringe must be injected under the skin within 5 minutes. Do not use the syringe if the needle touches any surface

### **Important information after the injection:**

- Do not rub the injection site after injection.
- **If you see drops of blood at the injection site, you can press a sterile cotton ball or gauze over the injection site for at least 10 seconds, until bleeding has stopped.**
- If you have bruising (small area of bleeding under the skin), an ice pack can also be pressed gently on the site. If bleeding does not stop, please contact your healthcare provider.

### **Disposing of the medicine and supplies:**

**Important: Always keep the sharps disposal container out of reach of children.**

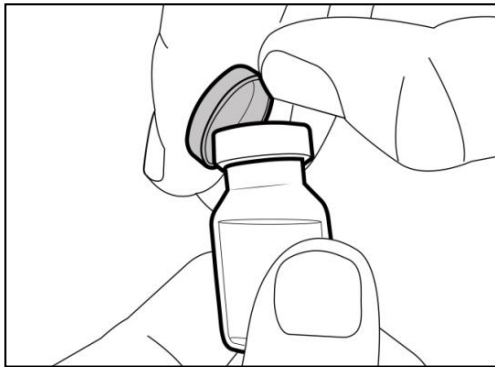
- **Throw away any used caps, vial(s), vial adaptors, needles and syringes in a sharps or puncture-proof container.**
- Put your used vial adaptors, needles and syringes in a sharps disposal container straight away after use. Do not throw away any loose caps, vials, needles and syringes in your household waste.
- If you do not have a sharps disposal container, you may use a household container that is:
  - made of heavy-duty plastic.
  - can be closed with a tight-fitting, puncture resistant lid, without sharps being able to come out.
  - upright and stable during use.
  - leak-resistant.
  - properly labelled to warn of hazardous waste inside the container.

- When your sharps disposal container is almost full, you will need to follow your local guidelines for the right way to throw away of your sharps disposal container.
- Do not throw away any used sharps disposal container in your household waste unless your local guidelines permit this. Do not recycle your used sharps disposal container.

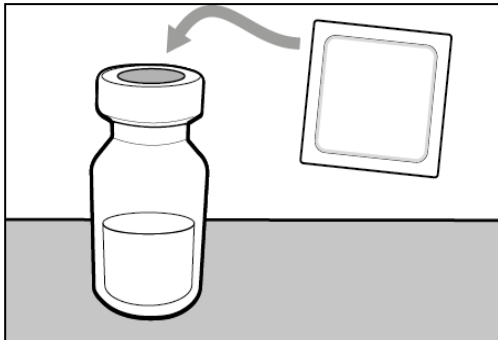
## 1. PREPARATION

### Step 1. Remove vial cap and clean top

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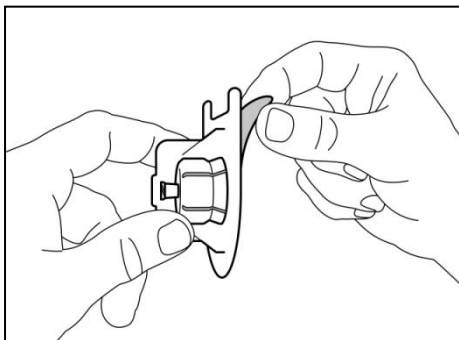
- Take the cap off the vial(s).
- Throw away the vial cap(s) into the sharps disposal container.



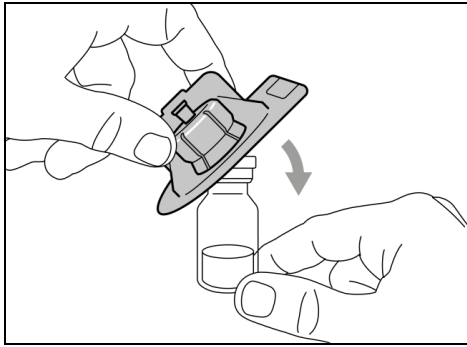
- Clean the top of the vial(s) stopper with an alcohol wipe.

### Step 2. Insert vial adaptor onto vial

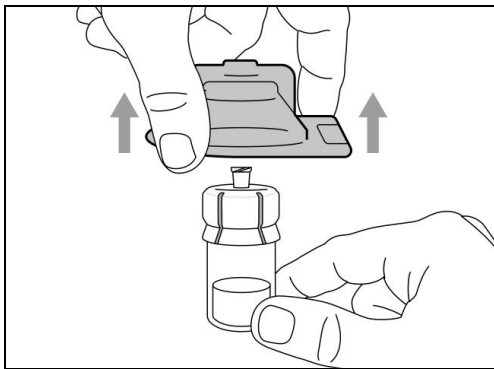
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- Peel off back to open the blister pack.
- ⚠ Do not remove the vial adaptor from the clear plastic blister pack.**



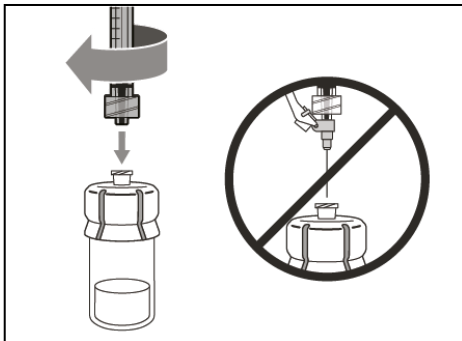
- Firmly press down the plastic blister pack with the vial adaptor onto the new vial at an angle, until you hear a “click”.



- Remove and throw away the plastic blister pack.
- **Do not** touch the tip of vial adaptor.

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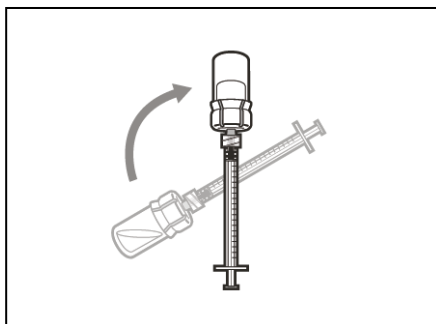
### Step 3. Connect syringe to vial adaptor



- **Remove syringe cap** (if required).
- **Push and twist the syringe clockwise** on to the vial adaptor until it is fully attached.

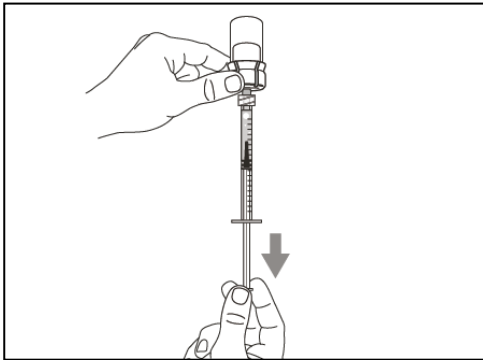
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### Step 4. Transfer medicine to syringe



- Keep the vial adaptor attached to the syringe and turn the vial upside down.

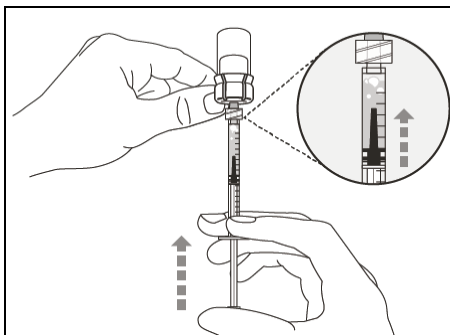




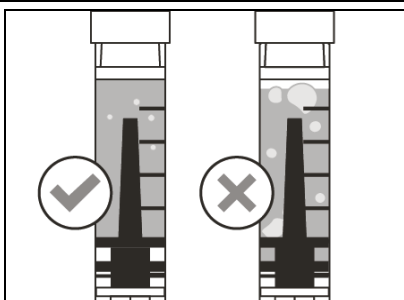
- With the syringe pointing upwards, slowly pull back the plunger to **fill the syringe with** more than the amount **of medicine** needed for your prescribed dose.
- **Hold plunger firmly** to ensure it does not pull back in.
- Be careful not to pull the plunger out of the syringe.

**Important:** If your prescribed dose is more than the amount of Hemlibra in the vial, **withdraw all medicine** and go to the “**Combining Vials**” section now

### Step 5. Remove air bubbles



- Keep the vial attached to the syringe and **check the syringe for larger air bubbles**. Large air bubbles can reduce the dose you receive.



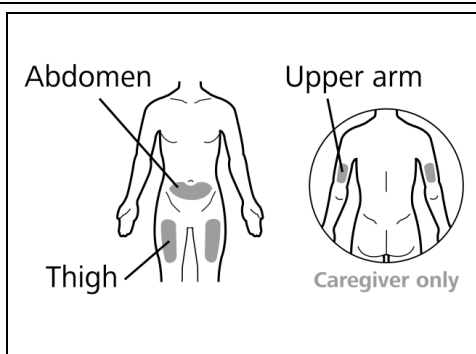
- **Remove the larger air bubbles** by gently **tapping** the syringe barrel with your finger until the air bubbles rise to the top of the syringe. **Slowly push the plunger** to push the large air bubbles out of the syringe.
- If the amount of medicine in the syringe is now at or below your prescribed dose, slowly pull back the plunger until you have **more** than the amount of medicine needed for your **prescribed dose**.
- Be careful not to pull the plunger out of the syringe.

- Repeat the steps above until you have removed the large air bubbles.

**Note:** Ensure you have enough medicine in the syringe to complete your dose before moving on to the next step.

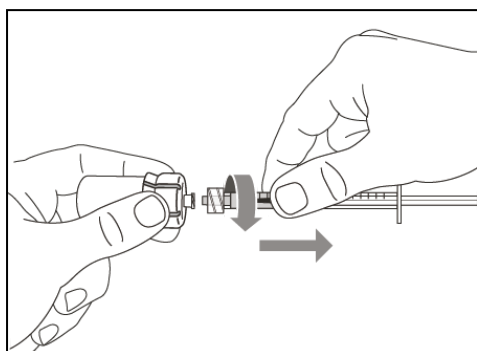
## 2. INJECTION

### Step 6. Clean injection site



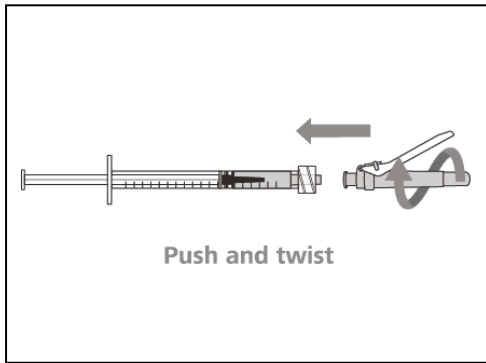
- Select and **clean** your injection site with an alcohol wipe.

### Step 7. Remove syringe from vial adaptor



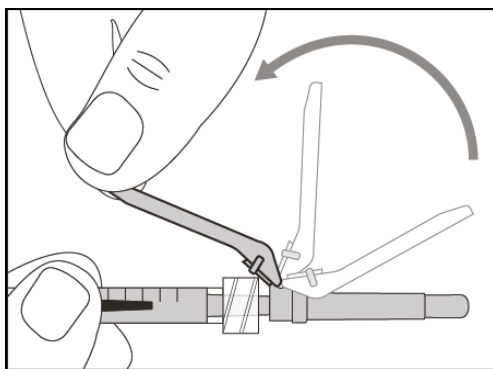
- Remove the syringe from the vial adaptor by twisting anticlockwise and gently pulling.
- Throw away the used vial/vial adaptor into a sharps disposal container.

### Step 8. Attach injection needle to syringe



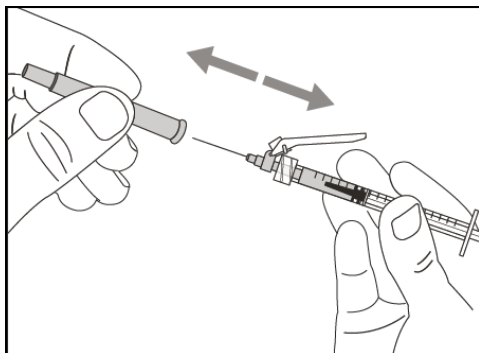
- Push and twist the injection needle clockwise onto the syringe until it is fully attached.
- **Do not** insert the injection needle into vial adaptor or use the injection needle to withdraw medicine from vial.

### Step 9. Move safety shield



- Move the safety shield away from the needle and towards the syringe barrel.

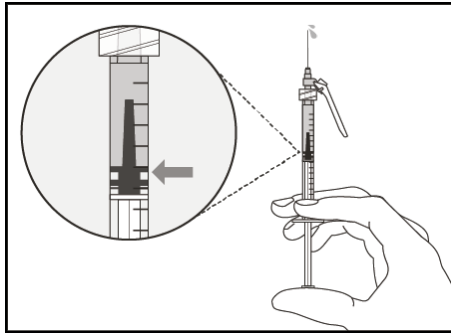
### Step 10. Uncap injection needle



- **Carefully** pull the injection needle cap **straightaway** from the syringe.
- Throw away the cap into a sharps disposal container.
- **Do not touch** the needle tip or allow it to touch any surface.
- After the injection needle cap has been removed, the medicine in the syringe must be injected within 5 minutes.

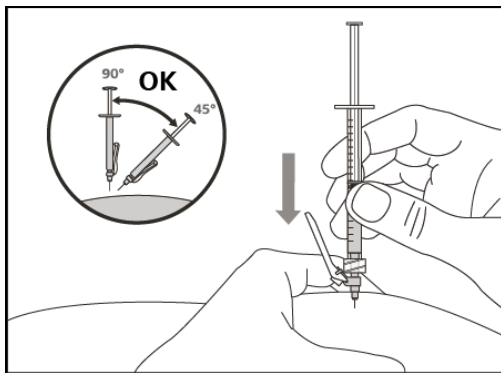
### Step 11. Adjust plunger to prescribed dose

- Hold the syringe with the needle pointing up and slowly push the plunger to your prescribed dose.
- **Check your dose**, ensure the top rim of the plunger is in line with the mark on the



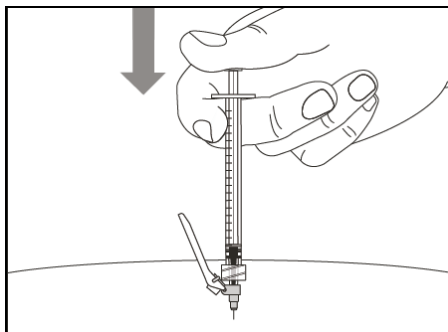
syringe for your prescribed dose.

### Step 12. Subcutaneous (under the skin) injection



- Pinch the selected injection site and fully insert the needle at a **45° to 90°** angle with a quick, firm action. **Do not** hold or push on the plunger while inserting the needle.
- Hold the position of the syringe and let go of the pinched injection site.

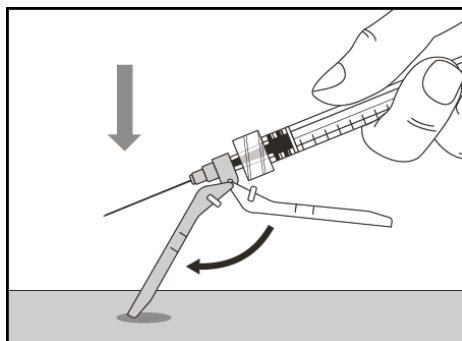
### Step 13. Inject the medicine



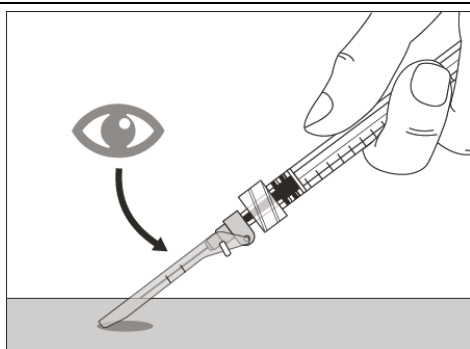
- Slowly inject all of the medicine by gently pushing the plunger all the way down.
- Remove the needle and syringe from the injection site at the same angle as inserted.

## 3. DISPOSAL

### Step 14. Cover needle with safety shield

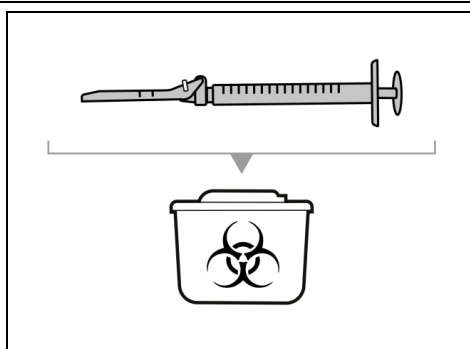


- Move the safety shield forward 90°, away from the syringe barrel.
- **Holding the syringe with one hand, press the safety shield down** against a flat surface with a firm, quick motion until you hear a “click”.



- If you do not hear a click, look to see that the needle is fully covered by the safety shield.
- Keep your fingers behind the safety shield and away from the needle at all times.
- **Do not** detach the injection needle.

#### Step 15. Throw away the needle and syringe



- Put your used needles and syringes in a sharps disposal container right away after use. For further information refer to the section “Disposing of the medicine and supplies”.
- **Do not** try to remove the used injection needle from the used syringe.
- **Do not recap** the injection needle with the cap.
- **Important:** Always keep the sharps disposal container out of reach of children.
- Throw away any used caps, vial(s), vial adaptors, needles and syringes in a sharps or puncture-proof container.

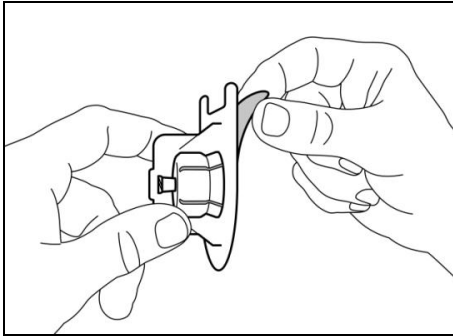
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## Combining Vials

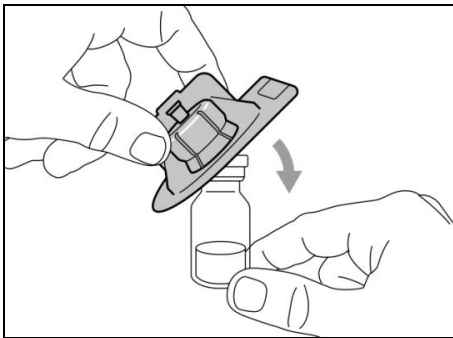
If you need to use more than 1 vial to get to your prescribed dose, follow these steps after you have drawn up the medicine from the first vial:

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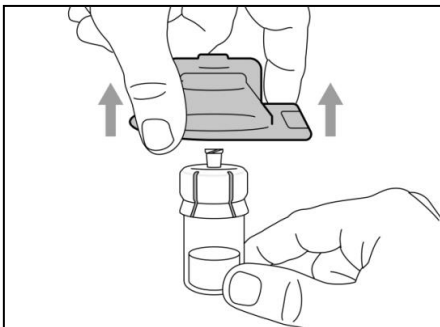
### Step A. Insert new vial adaptor into new vial



- Peel off back to open the blister pack.
- ⚠ **Do not remove the vial adaptor from the clear plastic blister pack.**



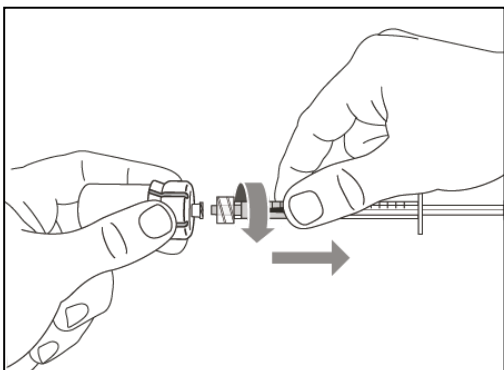
- Firmly press down the plastic blister pack with the vial adaptor onto the new vial at an angle, until you hear a **'click'**.



- Remove and throw away the plastic blister pack.
- **Do not touch the tip of vial adaptor.**

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### Step B. Remove used vial adaptor

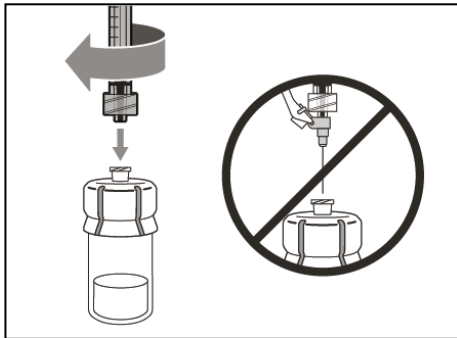


- Remove the used vial adaptor from the syringe by twisting anticlockwise and gently pulling.
- Throw away the used vial/vial adaptor into a sharps disposal container.

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### Step C. Connect new vial adaptor to syringe

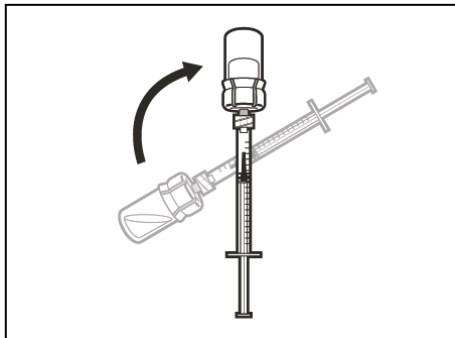
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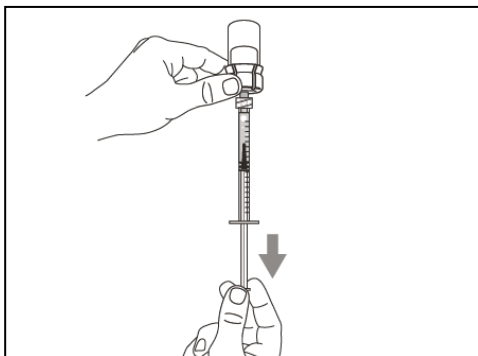
- **Push and twist the syringe clockwise** on to the vial adaptor until it is fully attached.

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### Step D. Transfer medicine into syringe



- Keep the vial adaptor attached to the syringe and turn the vial upside down.



- With the syringe pointing upwards, slowly pull back the plunger to **fill the syringe with** more than the amount **of the medicine** needed for your prescribed dose.
- **Hold plunger firmly** to ensure it does not pull back in.
- Be careful not to pull the plunger out of the syringe.

**Note:** Ensure you have enough medicine in the syringe to complete your dose before moving on to the next step.



**Repeat steps A to D with each additional vial until you have more than the amount of medicine needed for your prescribed dose. Once completed, keep the vial adaptor onto the vial and return to Step 5 “Remove air bubbles”. Continue with the remaining steps.**



## PASIËNTINLIGTINGSBLAADJIE

### **WAARSKUWING: TROMBOTIESE MIKRO-ANGIOPATIE en TROMBO-EMBOLISME**

Gevalle van trombotiese mikro-angiopatie en trombotiese voorvalle is aangemeld waar 'n gemiddelde kumulatiewe hoeveelheid van >100 e/kg/24 uur van geaktiveerde protrombienkomplekskonsentraat toegedien is vir 24 uur of langer aan pasiënte wat Hemlibra-profilakse ontvang. Monitor vir die ontwikkeling van trombotiese mikro-angiopatie en trombotiese voorvalle indien geaktiveerde protrombienkomplekskonsentraat (aPCC) toegedien word. Staak aPCC en onderbreek dosering van Hemlibra indien simptome voorkom. Veiligheidsdata is beperk en word gemonitor.

### **SKEDULERINGSTATUS**

**S4**

**Hemlibra® 30 mg/1 mL- oplossing vir inspuiting**

**Hemlibra® 60 mg/0,4 mL- oplossing vir inspuiting**

**Hemlibra® 105 mg/0,7 mL- oplossing vir inspuiting**

**Hemlibra® 150 mg/1 mL- oplossing vir inspuiting**

Suikervry

**Lees hierdie hele blaadjie noukeurig deur voor u begin om Hemlibra te gebruik.**

- Hou hierdie blaadjie. U moet dit dalk weer lees.
- As u verdere vrae het, vra asseblief vir u dokter of u apteker.
- Hemlibra is vir u persoonlik voorgeskryf en u behoort nie u medisyne met enige iemand te deel nie. Dit kan hulle benadeel, selfs al is hulle simptome dieselfde as u s'n.

## **Wat in hierdie blaadjie is**

1. Wat Hemlibra is en waarvoor dit gebruik word
2. Wat u moet weet voor u Hemlibra ontvang
3. Hoe om Hemlibra te gebruik
4. Moontlike newe-effekte
5. Hoe om Hemlibra te stoor
6. Inhoud van die pakkie en ander inligting
7. Gebruiksaanwysings

### **1. Wat Hemlibra is en waarvoor dit gebruik word**

#### **Wat Hemlibra is**

Hemlibra behoort aan 'n groep medisyne genaamd "monoklonale teenliggame".

Monoklonale teenliggame is 'n tipe proteïen wat 'n teiken in die liggaam herken en daaraan bind.

#### **Waarvoor Hemlibra gebruik word**

Hemlibra word gebruik vir die behandeling van pasiënte van alle ouderdomme met:

- óf hemofilie A wat faktor VIII-remmers ontwikkel het,
- óf erge hemofilie A wat nie faktor VIII-remmers ontwikkel het nie (die FVIII-bloedvlak is minder as 1%).

Hemofilie A is 'n oorerflike toestand wat veroorsaak word deur 'n tekort aan faktor VIII, 'n noodsaaklike stof wat nodig is vir bloed om te stol en om enige bloeding te stop.

Hemlibra verhinder bloeding of verminder bloei-episodes in mense met hierdie toestand.

Sommige pasiënte met hemofilie A kan faktor VIII-remmers (teenliggame teen faktor VIII) ontwikkel wat die vervangingsfaktor VIII keer om te werk.

#### **Hoe Hemlibra werk**

Hemlibra herstel die funksie van ontbrekende faktor VIII wat nodig is vir doeltreffende bloedstolling. Sy struktuur verskil van faktor VIII, dus word Hemlibra nie geraak deur faktor VIII-remmers nie.

## 2. Wat u moet weet voor u Hemlibra ontvang

### Hemlibra moet nie aan u toegedien word as:

U hipersensitief (allergies) is vir emicizumab of vir enige van die ander bestanddele van Hemlibra nie.

### Waarskuwings en voorsorgmaatreëls

**Voor u Hemlibra begin gebruik, is dit baie belangrik dat u met u dokter praat oor wanneer en hoe om “omleidingsagente” te gebruik terwyl u Hemlibra ontvang, aangesien dit kan verskil van vantevore.** Voorbeelde van omleidingsagente sluit in “geaktiveerde protrombienkomplekskonsentraat” (aPCC, ook genoem FEIBA) en “ekombinante FVIIa” (rFVIIa, ook genoem NovoSeven). Ernstige en potensieel lewensbedreigende newe-effekte is waargeneem wanneer aPCC (FEIBA) in pasiënte gebruik is wat ook Hemlibra ontvang.

**Wees bewus van die potensieel ernstige newe-effekte van geaktiveerde protrombienkomplekskonsentraat (aPCC) (FEIBA) gebruik terwyl u Hemlibra ontvang (sien “Moontlike newe-effekte”).**

#### ● Vernietiging van rooibloedselle (trombotiese mikro-angiopatie)

- trombotiese mikroangiopatie is 'n ernstige en potensieel lewensbedreigende toestand,
- as mense trombotiese mikroangiopatie het, kan die wande van die bloedvate beskadig word en bloedklonte kan moontlik in klein bloedvate ontwikkel. In sekere gevalle kan dit skade aan die niere en/of ander organe veroorsaak,
- dit is belangrik om die simptome van trombotiese mikroangiopatie te ken, ingeval u die toestand ontwikkel (sien “Moontlike newe-effekte” vir 'n lys simptome).

**Hou op om Hemlibra en geaktiveerde protrombienkomplekskonsentraat (aPCC) (FEIBA) te gebruik en praat dadelik met 'n dokter as u of u versorger enige simptome van trombotiese mikroangiopatie opmerk.**

#### ● Bloedklonte (trombo-embolisme)

- bloedklonte kan moontlik vorm. 'n Bloedklont kan bloedvate blokkeer en kan lewensbedreigend wees

- dit is belangrik om die simptome van bloedklonte te ken, ingeval klonte ontwikkel (sien “Moontlike newe-effekte” vir ’n lys simptome).

**Hou op om Hemlibra en geaktiveerde protrombienkomplekskonsentraat (aPCC) (FEIBA) te gebruik en praat dadelik met ’n dokter** as u of u versorger enige simptome van bloedklonte opmerk.

#### **Vorming van teenliggame (immunogenisiteit)**

- in seldsame gevalle kan jy teenliggame teen hierdie medisyne ontwikkel en dit kan dalk ophou om vir jou te werk.
- jy kan dalk opmerk dat bloeding nie met jou voorgeskrewe dosis van hierdie medisyne beheer word nie.

**Praat onmiddellik met ’n dokter** as jy of jou versorger opmerk dat Hemlibra nie meer vir jou werk nie (bv. ’n toename in bloedings). Jou dokter sal dalk jou behandeling moet verander as Hemlibra ophou om vir jou te werk.

#### **Kinders jonger as 1 jaar**

Die bloedstelsel ontwikkel steeds by kinders jonger as een jaar oud. Indien u kind jonger as een jaar oud is, kan u dokter Hemlibra slegs voorskryf ná die verwagte voordele en risiko’s van die gebruik van hierdie produk sorgvuldig opgeweeg is.

#### **Ander medisynes en Hemlibra**

Vertel altyd u gesondheidsorgkundige as u enige ander medisyne neem. (Dit sluit aanvullende of tradisionele medisyne in).

- **Om ’n omleidingsagens te gebruik terwyl u Hemlibra ontvang**

- **Voor u Hemlibra begin gebruik, praat met u dokter en volg hulle instruksies noukeurig oor wanneer om ’n omleidingsagens te gebruik en die dosis en skedule wat u moet gebruik.**

Hemlibra verhoog die vermoë van u bloed om te stol. Daarom kan die dosis van die omleidingsagens wat nodig word, dalk laer wees as die dosis wat u gebruik het voor u Hemlibra begin het.

- **Probeer om nie geaktiveerde protrombienkomplekskonsentraat (aPCC) (FEIBA) te gebruik nie**, tensy geen ander behandelingsopsies beskikbaar is nie. Indien aPCC (FEIBA) egter benodig word, praat met u dokter as u voel dat u meer as 50 eenhede/kg aPCC (FEIBA) in totaal benodig. Vir meer inligting oor die gebruik van aPCC (FEIBA) terwyl u Hemlibra ontvang, sien “Wat u moet weet voor u Hemlibra gebruik”, en wees bewus van die potensieel ernstige newe-effekte daarvan om aPCC (FEIBA) te gebruik terwyl u Hemlibra ontvang.

### **Laboratoriumtoetse**

Vertel u dokter as u Hemlibra gebruik voor u laboratoriumtoetse laat doen wat meet hoe goed u bloed stol. Die rede hiervoor is dat die teenwoordigheid van Hemlibra in die bloed moontlik met sommige van hierdie laboratoriumtoetse kan inmeng en dalk tot onakkurate resultate kan lei.

### **Swangerskap en borsvoeding**

Indien u swanger is, dink dat u swanger is, of beplan om 'n baba te hê of u baba borsvoed, bespreek dit asseblief met u dokter, apteker of ander gesondheidsorgkundige voordat u Hemlibra begin ontvang.

- Moenie Hemlibra gebruik as u swanger is nie. U dokter sal die risiko vir u baba bespreek.
- U moet 'n doeltreffende metode van geboortebepanking (voorbehoeding) gedurende behandeling met Hemlibra en vir 6 maande ná u laaste inspuiting van Hemlibra gebruik.
- Moenie u baba borsvoed terwyl u behandeling met Hemlibra ontvang nie.

### **Motorbestuur en die gebruik van masjinerie**

Hemlibra sal waarskynlik nie u vermoë om masjiene te gebruik of om te bestuur, aantas nie.

## **3. Hoe om Hemlibra te gebruik**

'n Mediese praktisyn wat gekwalifiseerd is om vir pasiënte met hemofilie te sorg, sal u op behandeling met Hemlibra begin. Hemlibra moet altyd geneem word soos deur u dokter voorgeskryf. U moet u dokter of apteker raadpleeg as u nie seker is nie.

Elke keer wat u Hemlibra gebruik, teken die naam en lotnommer van die medisyne aan.

### **Hoeveel Hemlibra om te gebruik**

### **Eerste dosis**

- Week 1 tot 4: Die dosis is 3 milligram vir elke 1 kg wat u weeg, ingespuut onder die vel (onderhuids) een keer per week.

### **Instandhoudingsdosisse**

Van week 5 af en daarna: Die dosis Hemlibra hang af van u gewig en u dokter moet u sê hoeveel om in te spuit. Die dosis is:

- 1,5 mg/kg een keer per week, of
- 3 mg/kg elke twee weke, of
- 6 mg/kg elke vier weke

### **Hoe Hemlibra toegedien word**

**As u of u versorger Hemlibra inspuut, moet u die instruksies onder “Instruksies vir gebruik” hier onder noukeurig lees en volg.**

- Hemlibra word as 'n inspuiting onder die vel gegee (onderhuids).
- U dokter of verpleegkundige sal vir u en/of u versorger wys hoe om Hemlibra in te spuit.
- Sodra u en/of u versorger opgelei is, behoort u self of met die hulp van 'n versorger hierdie medisyne tuis te kan inspuut.
- Moenie Hemlibra in 'n aar of 'n spier inspuut nie. Om die naald korrek onder die vel in te druk, knyp 'n vou los vel met u oop hand by die skoon inspuutingsplek vas. Dit is belangrik om die vel vas te knyp om seker te maak dat u onder die vel (in vetagtige weefsel) inspuut maar nie dieper (in spier) nie. Insputing in 'n spier kan tot 'n ongemaklike insputing lei
- Berei die insputing voor en dien dit onder skoon en kiemvrye toestande toe deur die “aseptiese tegniek” te gebruik. U sal meer inligting hieroor van u dokter of verpleegkundige ontvang
- Voor u Hemlibra gebruik, gaan die oplossing na vir deeltjies of verkleuring. Die oplossing moet kleurloos tot effens geel wees. Moenie Hemlibra gebruik indien u sien dat dit troebel of verkleurd is, of sigbare deeltjies bevat nie.

### **Waar om Hemlibra in te spuit**



- U dokter sal vir u en/of u versorger wys watter plekke op die liggaam met Hemlibra ingespuut moet word.
- Gee slegs 'n inspuiting op die aanbevole plekke: die voorkant van die middellyf (lae buik), buite op die bo-arms, of die voorkant van die dye. Gee slegs 'n inspuiting op die aanbevole plekke
- Elke keer wat u of u versorger 'n inspuiting gee, gebruik 'n ander plek op die liggaam as die een wat u voorheen gebruik het, op een van die aanbevole plekke (voorkant van die middellyf, buite op die bo-arms, of die voorkant van die dye).
- Moenie inspuitings gee waar die vel rooi, gekneus, teer of hard is, of plekke waar daar moesies of letsels is nie.
- Wanneer u Hemlibra gebruik, moet ander medisyne wat onder die vel ingespuut word, op 'n ander plek gegee word.

#### **Gebruik van spuite en naalde**

- 'n Spuit, 'n oordragnaald met filter of oordragnaald, en 'n inspuitingsnaald word benodig om die Hemlibra-oplossing uit die flessie in die spuit op te trek en dit onder die vel in te spuit.
- Spuite, oordragnaalde met filter, oordragnaalde en inspuitingsnaalde word nie in hierdie pakkie verskaf nie. Vir meer inligting, sien “Hoe Hemlibra lyk en die inhoud van die pakkie”
  - Wat benodig word om Hemlibra toe te dien en nie in hierdie pakkie is nie.
- Maak seker dat u 'n nuwe inspuitingsnaald gebruik vir elke inspuiting en dat u dit ná 'n enkele dosis weggooi.
- 'n 1 ml-spuut moet gebruik word vir 'n inspuiting van tot 1 ml Hemlibra-oplossing.
- 'n 2 ml- tot 3 ml-spuut moet gebruik word vir 'n inspuiting meer as 1 ml en vir tot 2 ml Hemlibra-oplossing.
- Wanneer dit saam met 'n flessiepasstuk gebruik word, moet 'n kleindooiespasiesuierspuut gebruik word.

U dokter sal u inlig hoe lank u behandeling met Hemlibra sal duur. Moenie behandeling stop sonder om u dokter te raadpleeg nie. Indien u van mening is dat die effek van Hemlibra te sterk of te swak is, vertel u dokter of apteker.

### **Gebruik by kinders en adolessente**

Hemlibra kan by kinders en adolessente van alle ouderdomme gebruik word (sien “Hoe om Hemlibra te gebruik” vir die aanbevole dosis).

As 'n kind die medisyne self wil inspuit, moet die kind se gesondheidsorgverskaffer en die ouer of versorger instem of dit gepas is vir hulle om dit te doen. Selfinspuiting vir kinders onder die ouderdom van 7 word nie aanbeveel nie.

### **As u meer Hemlibra gebruik as wat u moet**

In die geval van oordosering, raadpleeg u dokter of apteker. As nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Indien u of u versorger meer Hemlibra gebruik as wat u veronderstel is om te gebruik, vertel dadelik u dokter. Die rede hiervoor is dat u moontlik die risiko kan loop om nuwe-effekte soos



bloedklonte te ontwikkel. Gebruik altyd Hemlibra presies soos u dokter vir u gesê het, en maak seker by u dokter, apteker of verpleegkundige as u nie seker is nie.

#### **Indien u vergeet om Hemlibra te neem**

Indien u u geskeduleerde inspuiting vergeet, spuit die oorgeslane dosis so gou as moontlik ongeveer 24 uur voor die dag van die volgende geskeduleerde dosis in. Gaan dan voort om die medisyne een keer per week in te spuit soos geskeduleer. Moenie 'n dubbele dosis inspuit om op te maak vir 'n oorgeslane dosis nie.

Indien u nie seker is wat om te doen nie, vra u dokter, apteker of verpleegkundige.

#### **Indien u ophou om Hemlibra te neem**

Moenie ophou om Hemlibra te gebruik sonder om met u dokter te praat nie. Indien u ophou om Hemlibra te gebruik, sal u moontlik nie meer teen bloeding beskerm word nie.

Indien u enige verdere vrae oor die gebruik van Hemlibra het, vra u dokter, apteker of verpleegkundige.

#### **4. Moontlike nuwe-effekte**

Hemlibra kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir Hemlibra aangemeld is, is by hierdie blaadjie ingesluit nie. Indien u algemene gesondheid verswak of u enige ongewenste effekte ervaar terwyl u Hemlibra neem, raadpleeg asseblief u dokter, apteker of gesondheidsorgkundige vir raad.

**Ernstige nuwe-effekte van die gebruik van geaktiveerde protrombinkomplekskonsentraat (aPCC) (FEIBA) terwyl u Hemlibra ontvang**

**Hou op om Hemlibra en aPCC (FEIBA) te gebruik en praat dadelik met 'n dokter** indien u of u versorger enige van die volgende nuwe-effekte opmerk:

- **Vernietiging van rooibloedselle (trombotiese mikro-angiopatie):**
  - verwarring

- swakheid,
- swelling van die arms en bene,
- vergeling van vel en oë,
- vae buik- of rugpyn, voel siek (naarheid),
- braking (opgooi) of
- verminderde urinering

Hierdie simptome kan tekens wees van trombotiese mikro-angiopatie.

• **Bloedklonte (trombo-embolisme):**

- swelling, warm gevoel, pyn of rooiheid – hierdie simptome kan moontlik tekens van 'n bloedklont in 'n aar naby die oppervlak van die vel wees,
- hoofpyn, dooie gevoel in u gesig, oogpyn of -swelling of swak sig – hierdie simptome kan tekens wees van 'n bloedklont in 'n aar agter u oog,
- vel wat swart word – hierdie simptome kan 'n teken wees van erge skade aan die velweefsel.

**Hou op om Hemlibra en geaktiveerde protrombienkomplekskonsentraat (aPCC) (FEIBA) te gebruik en praat dadelik met 'n dokter** as u of u versorger enige van die nuwe-effekte wat hierbo gelys word, opmerk.

**Ander nuwe-effekte wanneer u Hemlibra gebruik**

**Algemeen:**

- hoofpyn
- gewrigpyn
- 'n reaksie op die plek waar die inspuiting gegee is (rooiheid, jeukerigheid, pyn)
- koors
- spierpyn
- diarree
- trombotiese mikro-angiopatie (skade aan bloedvate)
- jeukerige uitslag of jeukbulte (urtikarie)
- uitslag

### **Minder gereeld:**

- bloedklont in 'n aar agter u oog (kaverneuse sinustrombose)
- erge skade van die velweefsel (velnekrose)
- bloedklont in 'n aar naby die oppervlakte van die vel (oppervlakkige tromboflebitis)
- geswelde gesig, tong en/of keel en/of sukkel om te sluk, of jeukbulte, saam met moeilike asemhaling, wat op angio-edeem dui

Indien u enige newe-effekte opmerk wat nie in hierdie blaadjie genoem word nie, stel asseblief u dokter of apteker in kennis.

### **Aanmelding van newe-effekte**

As u newe-effekte ondervind, praat met u dokter of verpleegster. Dit sluit enige moontlike newe-effekte in wat nie in hierdie blaadjie genoem word nie. U kan ook newe-effekte aanmeld by SAHPRA via die aanmeldingsvorm vir ongewenste reaksie op middels ("6.04 Adverse Drug Reaction Reporting Form"), wat aanlyn onder SAHPRA se publikasies gevind kan word: <https://www.sahpra.org.za/Publications/Index/8>. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van Hemlibra te verskaf.

## **5. Hoe om Hemlibra te stoor**

- Bêre alle medisyne buite die bereik van kinders.
- Berg flessie in 'n yskas teen 2°C – 8°C.
- Moenie vries nie. Moenie skud nie.
- Hou die flessie in die buitenste boksie om dit teen sonlig te beskerm.
- Moenie Hemlibra ná die vervaldatum (EXP) op die pakkie gebruik nie.
- Sodra dit uit die yskas gehaal is, kan onoorgemaakte flessies teen kamertemperatuur (onder 30 °C) vir tot 7 dae gehou word.
- Ná berging teen kamertemperatuur kan onoorgemaakte flessies terug in die yskas gesit word. Kumulatiewe bewaringstyd teen kamertemperatuur moet nie 7 dae oorskry nie.
- Sodra Hemlibra vanaf die flessie na die spuit oorgedra is, moet dit dadelik gebruik word.
- Neem alle ongebruikte medisyne na u apteker terug.

- Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

## 6. Inhoud van die pakkie en ander inligting

### Wat Hemlibra bevat

- Die aktiewe middel is emicizumab. Elke flessie Hemlibra bevat 30 mg (1 ml teen 'n konsentrasie van 30 mg/ml), 60 mg (0,4 ml teen 'n konsentrasie van 150 mg/ml), 105 mg (0,7 ml teen 'n konsentrasie van 150 mg/ml) of 150 mg (1 ml teen 'n konsentrasie van 150 mg/ml) emicizumab.
- Die ander bestanddele is L-arginien, L-aspartiensuur, L-histidien, poloxamer 188 en water vir inspuiting.

### Hoe Hemlibra lyk en die inhoud van die pakkie

Hemlibra-oplossing is 'n kleurlose tot effens geel steriele, preserveermiddelvrye, en gereed-om-te-gebruik-oplossing vir onderhuidse inspuiting wat nie verdun hoef te word nie. Hemlibra-oplossing moet weggegooi word indien deeltjies sigbaar is of die produk verkleur is.

Hemlibra-oplossing vir inspuiting-flessies is slegs vir eenmalige gebruik.

Een 3 ml- tipe 1-flessie van deursigtige glas wat die volgende bevat:

- 1 ml Hemlibra-oplossing (30 mg/ml) of
- 0,4 ml Hemlibra-oplossing (150 mg/ml) of
- 0,7 ml Hemlibra-oplossing (150 mg/ml) of
- 1 ml Hemlibra-oplossing (150 mg/ml).

Elke pakkie Hemlibra bevat 1 glasflessie.

Nie alle sterktes word dalk bemark nie.

### Wat benodig word vir Hemlibra-toediening en nie in hierdie pakkie is nie

'n Spuit, 'n oordragnaald met filter of 'n oordragnaald of 'n flessiepasstuk en 'n inspuitingsnaald word benodig om die Hemlibra-oplossing uit die flessie op te trek en dit onder die vel in te spuit.

### Houer van registrasiesertifikaat

Roche Products (Edms.) Bpk.

Bekkerweg 90, Hertford Office Park



Gebou E, Vorna Vallei, Midrand,  
Johannesburg, 1686

Suid-Afrika

Roche etiekhulplyn (REAL), tolvry: 0800 21 21 25  
**Hierdie blaadjie is laas hersien op**

16 Julie 2024

### **Registrasienommer**

Hemlibra® 30 mg/1 ml: 53/30.1/0071

Hemlibra® 60 mg/0,4 ml: 53/30.1/0072

Hemlibra® 105 mg/0,7 ml: 53/30.1/0073

Hemlibra® 150 mg/1 ml: 53/30.1/0074

## **Gebruiksaanwysings**

### **Hemlibra®-inspuiting - Enkeldosisflessie(s)**

#### **OORDRAGNAALD MET FILTER**

#### **Opsie (om die Hemlibra van die flessie na die spuit oor te dra)**

U moet die instruksies vir gebruik lees, verstaan en volg voor u Hemlibra inspuit. U gesondheidsorgverskaffer moet u wys hoe om Hemlibra behoorlik voor te berei, af te meet en in te spuit voor u dit vir die eerste keer gebruik. Vra u gesondheidsorgverskaffer indien u enige vrae het.

#### **Belangrike inligting:**

- **Moenie** uself of iemand anders inspuit, tensy u deur u gesondheidsorgverskaffer gewys is hoe om dit te doen nie.
- Maak seker die naam Hemlibra is op die boksie en flessie-etiket.
- Voor u die flessie oopmaak, lees die flessie-etiket om seker te maak u het die korrekte medisynesterkte(s) om die dosis te gee wat vir u voorgeskryf is. U moet dalk meer as 1 flessie gebruik om uself die korrekte dosis te gee.

- Gaan die vervaldatum op die boksie en flessie-etiket na. **Moenie** gebruik indien die vervaldatum verby is nie.
- **Gebruik die flessie slegs een keer.** Nadat u u dosis ingespuut het, gooi enige ongebruikte Hemlibra wat oor is in die flessie weg. Moenie ongebruikte medisyne in die flessie vir latere gebruik bêre nie.
- **Gebruik net die spuite, oordragnaalde met filter, en inspuitingsnaalde wat u gesondheidsorgkundige voorskryf.**
- **Gebruik die spuite, oordragnaalde met filter en inspuitingsnaalde net een keer. Gooi enige ongebruikte spuite en naalde weg.**
- Indien u voorgeskrewe dosis meer as 2 ml is, sal u meer as een onderhuidse inspuiting Hemlibra moet kry; kontak u gesondheidsorgverskaffer vir die inspuitingsinstruksies.
- U moet Hemlibra slegs onder die vel inspuut.

#### **Hoe om Hemlibra-flessies, naalde en spuite te berg:**

- Hou die flessie in die oorspronklike boksie om die medisyne teen sonlig te beskerm.
- Hou die flessies, naalde en spuite buite die sig en bereik van kinders. Hou die flessie in die yskas.
- **Moenie** vries nie.
- **Moenie** die flessie skud nie.
- Haal die flessie 15 minute voor gebruik uit die yskas en laat dit kamertemperatuur (onder 30 °C) bereik voor u 'n inspuiting voorberei.
- Sodra dit uit die yskas gehaal is, kan die onoopgemaakte flessie vir tot 7 dae teen kamertemperatuur gehou word. Ná berging teen kamertemperatuur kan onoopgemaakte flessies terug in die yskas gesit word. Die totale hoeveelheid tyd buite koelbewaring en teen kamertemperatuur moet nie 7 dae oorskry nie.
- Gooi flessies weg wat vir langer as 7 dae teen kamertemperatuur gehou is, of wat in temperature bo 30 °C was.
- Hou die oordragnaald met filter, inspuitingsnaald en -spuit droog.

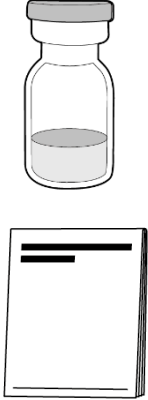
### Hoe om die medisyne en u benodighede na te gaan

- Maak alle benodighede wat hier onder gelys word, bymekaar om u inspuiting voor te berei en toe te dien.
- **Kontroleer** die vervaldatum op die boksie, op die flessie-etiket en op die benodighede wat hier onder gelys word. **Moenie gebruik** indien die vervaldatum verby is nie.

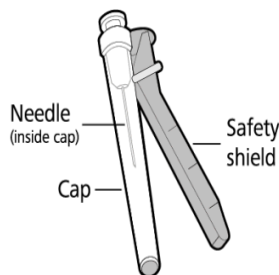
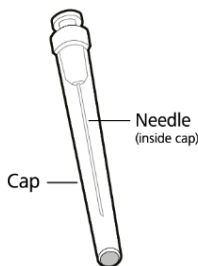
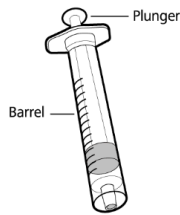
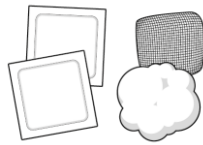
### Moenie die flessie gebruik indien:

- die medisyne troebel, wasig of verkleur is nie.
- die medisyne deeltjies bevat nie.
- die doppie wat die stopper bedek, weg is nie.
- Gaan die benodighede na vir skade. **Moenie gebruik** as dit beskadig lyk of as dit laat val is nie.
- Plaas die benodighede op 'n skoon, goed-beligte werksoppervlakte.

### INGESLUIT IN DIE BOKSIE:

	<ul style="list-style-type: none"><li>• <b>Flessie wat die medisyne bevat</b></li> <li>• Gebruiksaanwysings <b>vir Hemlibra</b></li></ul>
---	---

NIE IN DIE BOKSIE NIE:



- **Alkohollappies**

**Let wel:** As u meer as 1 flessie moet gebruik om u voorgeskrewe dosis in te spuit, moet u 'n nuwe alkohollappie vir elke flessie gebruik.

- **Gaas**

- **Watteballetjie**

- **Spuit**

**Let wel:** Vir inspuiting van tot 1 ml, gebruik 'n **1 ml-spuit**.

Vir inspuiting van tussen 1 ml en 2 ml, gebruik 'n **2 ml- of 3 ml-spuit**.

- **18G-oordragnaald met 5 mikrometer-filter**

**Let wel:** As u meer as 1 flessie moet gebruik om u voorgeskrewe dosis in te spuit, moet u 'n nuwe oordragnaald met filter vir elke flessie gebruik.

**Moenie** die oordragnaalde gebruik om medisyne in te spuit nie.

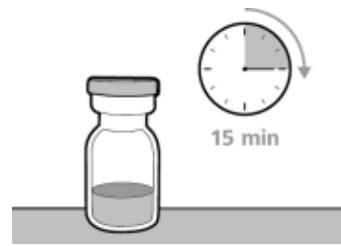
- **26G-inspuitingsnaald met naaldveiligheidstoestel**

**Moenie** die inspuitingsnaald gebruik om medisyne uit die flessie te trek nie.

**Weggooihouer vir skerppuntnaalde**



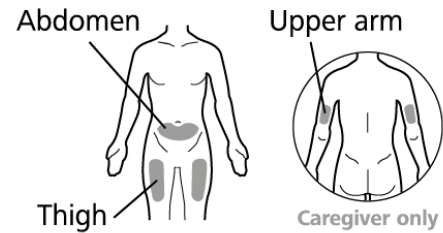
- Laat die flessie(s) toe om voor gebruik vir omtrent 15 minute kamertemperatuur te bereik op 'n skoon, plat oppervlakte weg van direkte sonlig.
- Moenie die flessie op enige ander manier probeer warm maak nie.
- **Was u hande** deeglik met seep en water.



**Figuur A**

## Hoe om 'n inspuitingsplek te kies en voor te berei:

- Maak die gekose inspuitingsplek met 'n alkohollappie skoon.
- Laat die vel vir omtrent 10 sekondes droog word. Moet nie voor u inspuiting aan die plek vat, dit droog waai of daarop blaas nie.



**Figuur B**

U kan die volgende plekke vir u inspuiting **gebruik**:

- Dy (voor en middel).
- Maagarea (buik), behalwe vir 5 cm rondom die naeltjie.
- Buite op die boarm (slegs as 'n versorger die inspuiting gee).
- U moet 'n ander inspuitingsplek gebruik vir elke inspuiting, wat ten minste 2,5 cm weg is van die plek wat u vir u vorige inspuiting gebruik het.
- Moenie op plekke inspuit wat deur 'n gordel of broekband geïrriteer kan raak nie. Moenie in moesies, letsels, kneusplekke, of plekke waar die vel teer, rooi en hard of waar die vel stukkend is, inspuit nie.

## Hoe om die spuit vir inspuiting voor te berei

- Moenie aan die oop naalde raak of dit op 'n oppervlak sit nadat die doppie afgehaal is nie.
- Sodra die spuit met die medisyne gevul is, moet die inspuiting onmiddellik gegee word.

- Sodra die inspuittingsnaald se doppie afgehaal is, moet die medisyne in die spuit binne 5 minute onder die vel ingespuut word. Moenie die spuit gebruik as die naald aan enige oppervlak raak nie.
- **Gooi enige gebruikte flessie(s), naalde, flessie-/inspuittingsnaalddoppies en gebruikte spuite in 'n skerppuntnaald-/prikbestande houer.**

#### **Belangrike inligting ná die inspuiting**

- Moenie die inspuittingsplek ná inspuiting vryf nie.
- **As u druppels bloed by die inspuittingsplek sien, kan u 'n steriele watte of gaas vir ten minste 10 sekondes op die inspuittingsplek druk totdat die bloeding gestop het.**
- As u kneusing (klein area wat onder die vel bloei) het, kan 'n yspak ook liggies op die plek gedruk word. As bloeding nie stop nie, kontak asseblief u gesondheidsorgverskaffer.

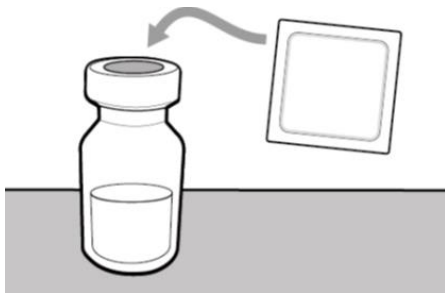
#### **Wegdoening van die medisyne en benodighede:**

#### **Belangrik: Hou altyd die weggooihouer vir skerppuntnaalde buite bereik van kinders.**

- Sit u gebruikte naalde en spuite dadelik in 'n weggooihouer vir skerppuntnaalde ná gebruik. Moenie enige los naalde en spuite in u huishoudelike afval weggooi nie.
- Indien u nie 'n weggooihouer vir skerppuntnaalde het nie, kan u 'n houer in die huis gebruik wat:
  - van swardiensplastiek gemaak is.
  - kan toemaak met 'n deksel wat dig toemaak en prikbestand is, sodat skerppuntnaalde nie kan uitval nie.
  - regop en stabiel gedurende gebruik is.
  - nie lek nie.
  - behoorlik gemerk is om te waarsku dat daar gevaarlike afval binne die houer is.
- Wanneer u weggooihouer vir skerppuntnaalde amper vol is, sal u u plaaslike riglyne moet volg vir die regte manier om u weggooihouer vir skerppuntnaalde weg te gooi.
- Moenie u weggooihouer vir skerppuntnaalde in u huishoudelike afval weggooi tensy u plaaslike riglyne dit toelaat nie. Moenie u gebruikte weggooihouer vir skerppuntnaalde herwin nie.

## 1. VOORBEREIDING

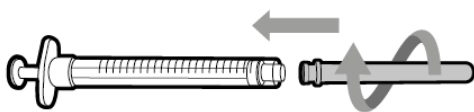
### Stap 1. Verwyder flessiedoppie en maak bokant skoon



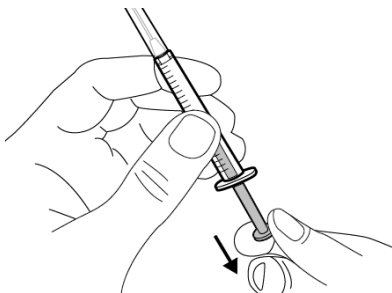
- Haal die doppie van die flessie(s) af.
- Gooi die flessiedoppie(s) in die weggoi-houer vir skerppuntnaalde.

- Maak die bokant van die flessie(s)-stopper met 'n alkohollappie skoon.

### Stap 2. Sit die oordragnaald met filter vas aan die spuit



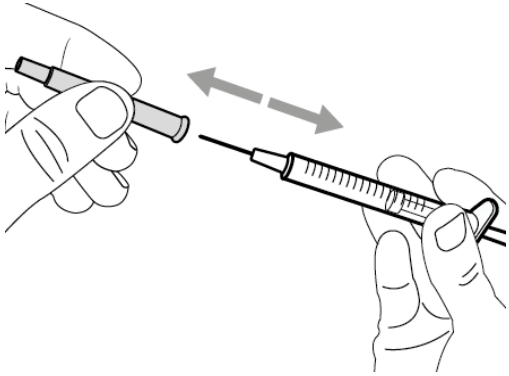
Push and twist



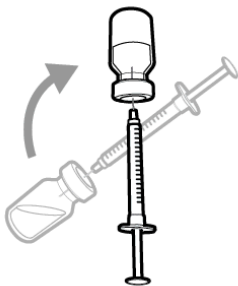
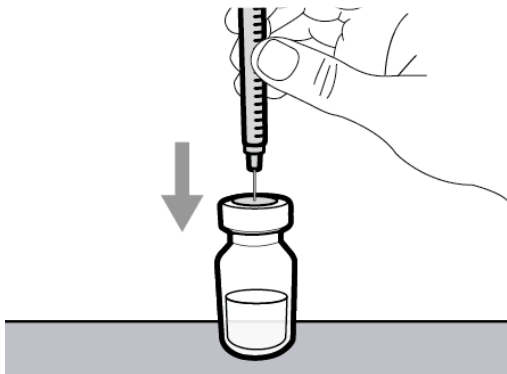
- **Druk en draai die oordragnaald met filter kloksgewys** op die spuit totdat dit heeltemal vas is.

- Trek die suier stadig terug en trek dieselfde hoeveelheid lug in die spuit in as u voorgeskrewe dosis.

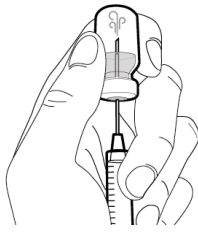
### Stap 3. Haal die oordragnaald met filter se doppie af



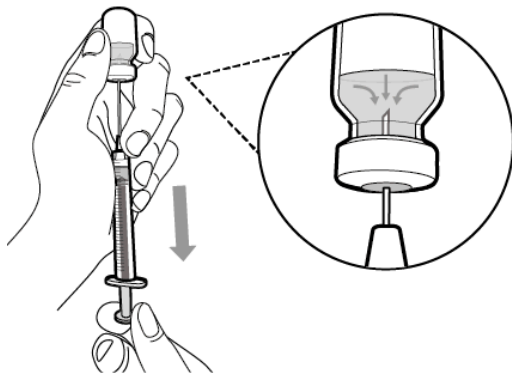
### Stap 4. Spuit lug in die flessie in



- Hou die spuit aan die buis vas met die oordragnaald met filter wat na bo wys.
- Trek die doppie van die oordragnaald met filter versigtig reguit en weg van u liggaam af. **Moenie die doppie weggooi nie. Plaas die doppie van die oordragnaald met filter op 'n plat oppervlak.** U sal die doppie weer op die oordragnaald met filter moet terugsit nadat u die medisyne oorgedra het.
- **Moenie aan die naaldpunt raak** of dit op 'n oppervlak sit nadat die naalddoppie afgehaal is nie.
- Hou die flessie op die plat werksoppervlakte en druk die oordragnaald met filter en -spuit reguit af in die middel van die flessiestopper in.
- Hou die naald in die flessie en draai die flessie onderstebo.



### Stap 5. Dra medisyne na spuit oor

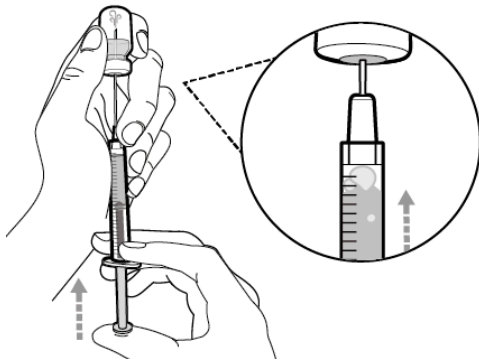


- Met die naald wat na bo wys, druk op die suier om die lug uit die spuitbo **die medisyne in te spuit**.
  - Hou u vinger gedruk op die spuitsuier.
  - **Moet nie** lug in die medisyne inspuit nie, want dit kan lugborrels of skuim in die medisyne veroorsaak.
  - Skuif die punt van die naald af sodat dit **binne-in die medisyne is**.
  - **Trek die suier stadig** terug om lugborrels/skuim te voorkom.
- Vul die spuit met meer as die hoeveelheid medisyne wat nodig is vir u voorgeskrewe dosis.
- Wees versigtig om nie die suier uit die spuit te trek nie.

**Belangrik:** As u voorgeskrewe dosis meer as die hoeveelheid medisyne in die flessie is, **trek al die medisyne** uit en gaan nou na die “**Hoe om flessies te kombineer**”-afdeling.

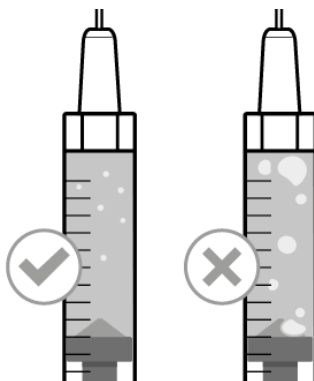
### Stap 6. Verwyder lugborrels

- Hou die naald in die flessie en gaan die spuit vir groter lugborrels na. Groot lugborrels kan die dosis verminder wat u ontvang.
- **Verwyder die groter lugborrels** deur liggies met u vingers aan die spuitbuis te



**tik** totdat die lugborrels na die bokant van die spuit styg. Skuif die punt van die naald **na bo die medisyne** en druk die suier stadig na bo om die lugborrels uit die spuit te stoot

- As die hoeveelheid medisyne in die spuit nou by of onder u voorgeskrewe dosis is, beweeg die punt van die naald **binne-in die medisyne** en trek die suier **stadig** terug tot u **meer** as die hoeveelheid medisyne het wat vir u **voorgeskrewe dosis** benodig word.
- Wees versigtig om nie die suier uit die spuit te trek nie.
- Herhaal die stappe hier bo totdat u die groter lugborrels verwyder het.



**Let wel:** Maak seker u het genoeg medisyne in die spuit om u dosis te voltooi voor u na die volgende stap gaan. As u nie al die medisyne kan verwyder nie, keer die flessie om om die res daarvan te bereik.

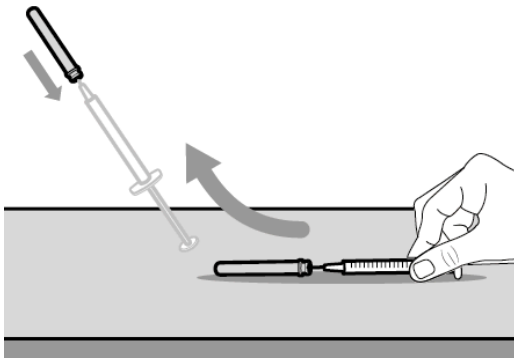


**Moet nie** die oordragnaald met filter gebruik om medisyne in te spuit nie, want dit kan

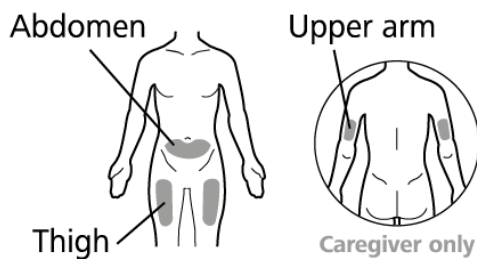
moontlik pyn en bloeding veroorsaak.

## 2. INSPUITING

### Stap 7. Sit weer die oordragnaald met filter se doppie op



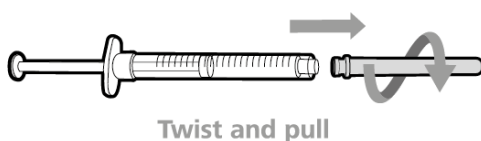
- Verwyder die spuit en oordragnaald met filter uit die flessie.
- **Gebruik een hand om die oordragnaald met filter in die doppie in te skuif en maak 'n skepbeweging na bo** om die naald te bedek.
- Sodra die naald bedek is, druk die doppie van die oordragnaald met filter met **een hand** na die spuit toe om dit heeltemal op te sit om te voorkom dat u u per ongeluk met die naald seermaak



- Kies en **maak u inspuitingsplek met 'n alkohollappie skoon.**

### Stap 8. Maak inspuitingsplek skoon

### Stap 9. Verwyder oordragnaald met filter



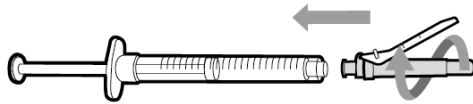
- Verwyder die oordragnaald met filter uit die spuit deur dit antikloksgewys te draai en saggies te trek.
- Gooi die gebruikte oordragnaald met filter in 'n weggooihouer vir skerppuntnaalde.



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**Stap 10. Sit inspuitingsnaald vas aan die spuit**

- Druk en draai die inspuitingsnaald kloksgewys op die spuit totdat dit heeltemal vassit.

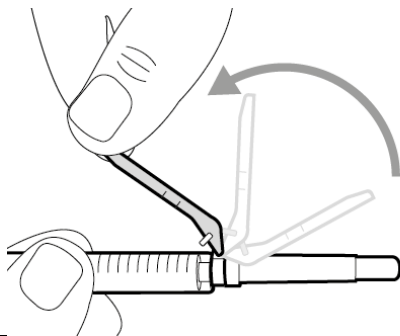


Push and twist

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**Stap 11. Skuif naaldveiligheidstoestel**

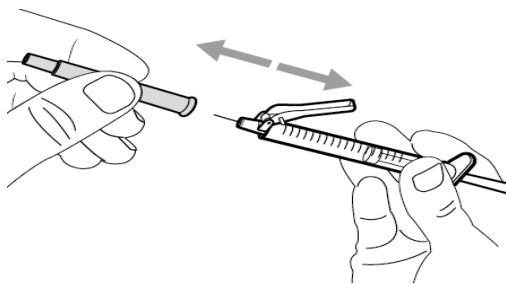
- Skuif die naaldveiligheidstoestel weg van die naald af en na die buis van die spuit toe.



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**Stap 12. Haal doppie van inspuitingsnaald af**

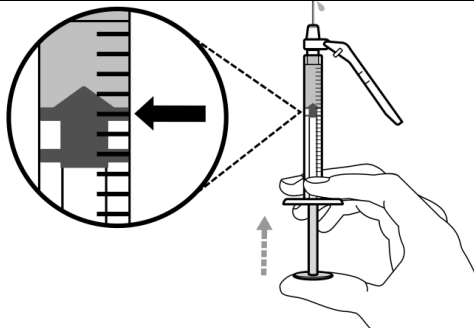
- **Trek die inspuitingsnaalddoppie versigtig** reguit weg van die spuit af.
- Gooi die doppie weg in 'n weggooihouer vir skerppuntnaalde.
- **Moenie aan die naaldpunt raak** of dit aan enige oppervlakte laat raak nie.
- Sodra die inspuitingsnaald se doppie afgehaal is, moet die medisyne in die spuit binne 5 minute ingespuut word.



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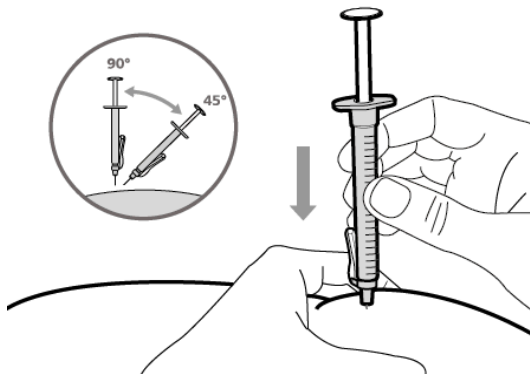
**Stap 13. Verstel suier na voorgeskrewe dosis**

- Hou die spuit met die naald wat opwaarts wys en druk die suier stadig tot by u voorgeskrewe dosis.
- **Kontroleer u dosis** deur seker te maak die



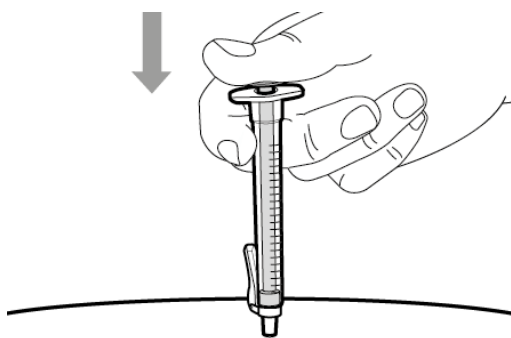
boonste rand van die suier is gelyk met die merk op die spuit vir u voorgeskrewe dosis.

### Stap 14. Onderhuidse (onder die vel) inspuiting



- Knyp die geselekteerde inspuitingsplek vas en steek die naald heeltemal teen 'n **45°- tot 90°-hoek** in met 'n vinnige, ferm aksie. **Moenie** die suier vashou of druk terwyl u die naald insteek nie.
- Hou die posisie van die spuit en laat los die vasgeknypte inspuitingsplek.

### Stap 15. Spuit die medisyne in

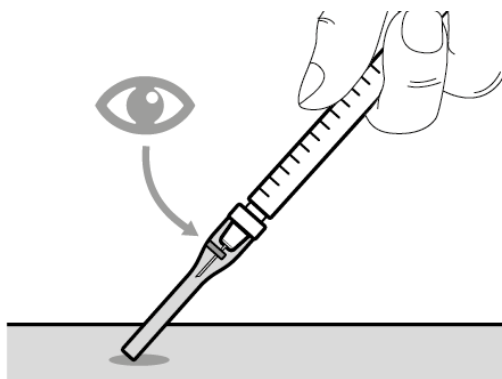
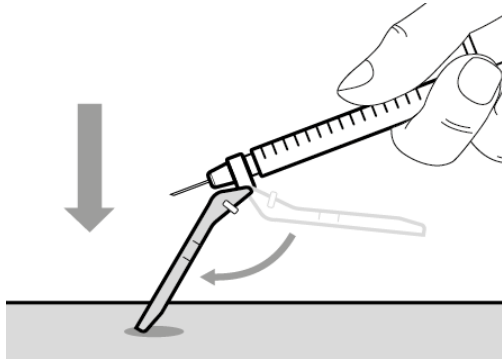


- Spuit al die medisyne in deur die suier saggies heeltemal af te druk.
- Haal die naald en spuit uit die inspuitingsplek teen dieselfde hoek as wat dit ingestek is.

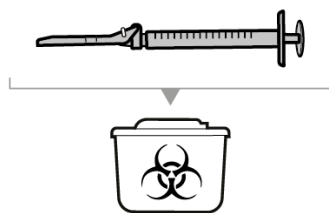
## 3. WEGDOENING

### Stap 16. Bedek naald met naaldveiligheidstoestel

- Skuif die naaldveiligheidstoestel 90° vorentoe, weg van die spuitbuis af.



**Stap 17. Gooi die naald en spuit weg.**



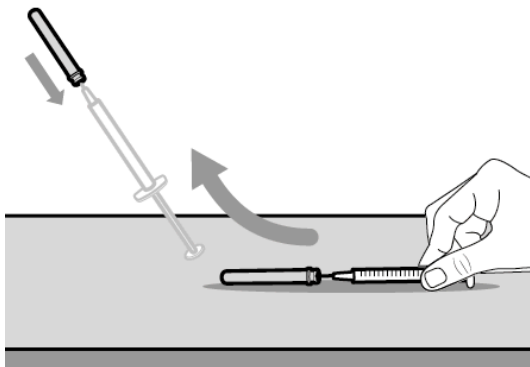
- Terwyl u die spuit met een hand vashou, **druk die naaldveiligheidstoestel af** teen 'n plat oppervlakte met 'n ferm, vinnige aksie tot u 'n “kliek” hoor.
- As u nie 'n kliek hoor nie, kyk om te sien of die naald heeltemal deur die naaldveiligheidstoestel bedek word.
- Hou u vingers altyd agter die naaldveiligheidstoestel en weg van die naald af.
- **Moet nie** die inspuitingsnaald losmaak nie
- Sit **u** gebruikte naalde en spuite in 'n weggooihouer vir skerppuntnaalde direk nadat u dit gebruik het. Vir verdere inligting, raadpleeg die afdeling “Wegdoening van die medisyne en benodighede”.
- **Moenie** die gebruikte inspuitingsnaald van die gebruikte spuit probeer verwyder nie.
- **Moenie die doppie weer** op die inspuitingsnaald sit nie.
- **Belangrik:** Hou altyd die weggooihouer vir skerppuntnaalde buite bereik van kinders.
- Gooi enige gebruikte doppies, flessie(s), naalde en spuite in 'n skerppuntnaald- of prikbestande houer.

## Hoe om flessies te kombineer

As u meer as 1 flessie benodig om u voorgeskrewe dosis te bereik, volg hierdie stappe nadat u die medisyne van die eerste flessie af opgetrek het:

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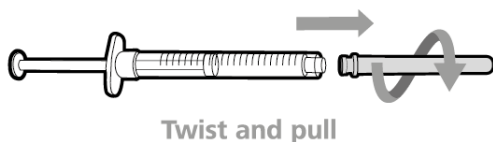
### Stap A. Sit weer die oordragnaald met filter se doppie op



- Verwyder die spuit en oordragnaald met filter uit die flessie.
- **Gebruik een hand om** die oordragnaald met filter in die doppie in te skuif en **maak 'n skepbeweging na bo** om die naald te bedek.
- Sodra die naald bedek is, druk die doppie van die oordragnaald met filter met **een hand** na die spuit toe om dit heeltemal op te sit om te voorkom dat u u per ongeluk met die naald seermaak.

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### Stap B. Verwyder oordragnaald met filter



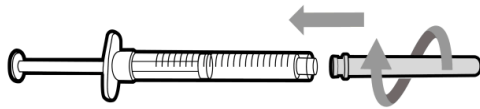
- Verwyder die oordragnaald met filter uit die spuit deur dit antikloksgewys te draai en saggies te trek.
- Gooi die gebruikte oordragnaald met filter in 'n weggooihouer vir skerppuntnaalde.

---

### Stap C. Sit 'n nuwe oordragnaald met filter aan die spuit

**Let wel: U moet 'n nuwe oordragnaald met filter gebruik elke keer wat u medisyne uit 'n nuwe flessie optrek.**

- Druk en draai die **nuwe** oordragnaald met filter kloksgewys op die spuit totdat dit heeltemal vas

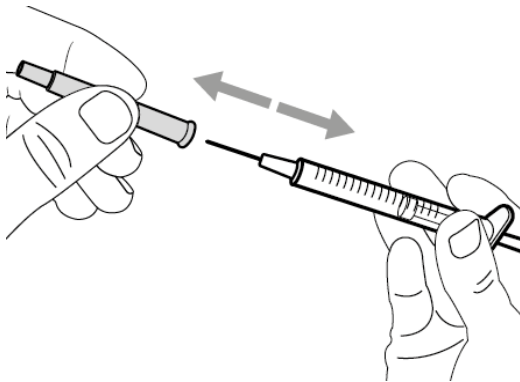


Push and twist

is.

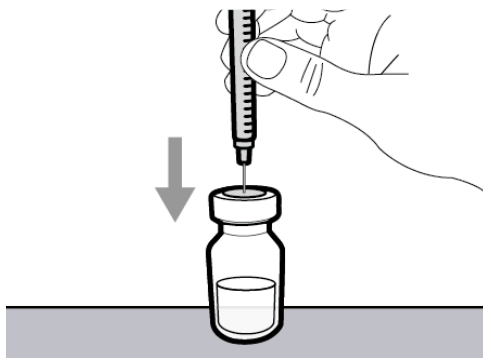
- Trek die suier stadig terug en trek 'n bietjie lug in die spuit in.

**Stap D. Haal die oordragnaald met filter se doppie af**



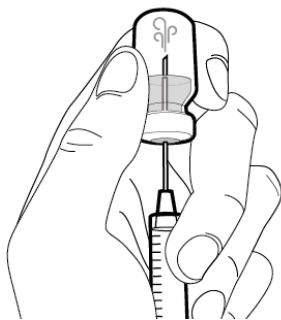
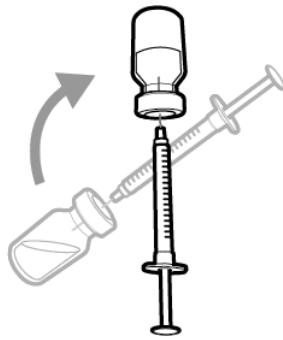
- Hou die spuit aan die buis vas met die oordragnaaldoppie wat na bo wys.
- Trek die doppie van die oordragnaald met filter versigtig reguit en weg van u liggaam af. **Moenie die doppie weggooi nie.** U sal die doppie weer op die oordragnaald met filter moet terugsit nadat u die medisyne uitgetrek het.
- **Moenie aan die naaldpunt raak nie.**

**Stap E. Spuit lug in die flessie in**



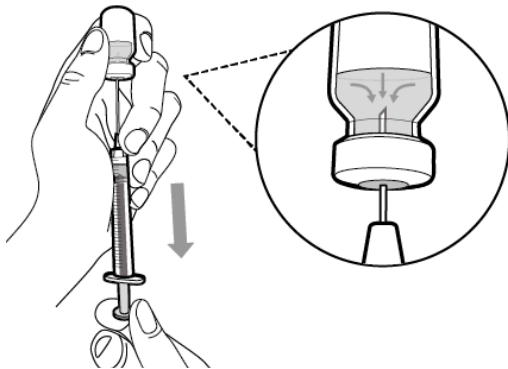
- Met die nuwe flessie op die plat werksoppervlakte, druk die oordragnaald met filter en spuit reguit af in die **middel** van die flessiestopper in.

- Hou die oordragnaald met filter in die flessie en draai die flessie onderstebo.



- Met die naald wat na bo wys, spuit die lug van die spuit af **bo die medisyne in**.
- Hou u vinger gedruk op die spuitsuier.
- **Moet nie** lug in die medisyne inspuit nie, want dit kan lugborrels of skuim in die medisyne veroorsaak.

#### Stap F. Dra medisyne na spuit oor



- Skuif die punt van die naald af sodat dit **binne-in die medisyne** is.
- **Trek die suier stadig** terug om lugborrels/skuim te voorkom.
- Vul die spuitbuis met meer as die hoeveelheid medisyne wat nodig is vir u voorgeskrewe dosis.
- Wees versigtig om nie die suier uit die spuit te trek nie.

**Let wel:** Maak seker u het genoeg medisyne in die spuit om u dosis te voltooi voor u na die volgende stappe gaan. As u nie al die medisyne kan verwyder nie, draai die flessie regop om die res daarvan te bereik.



**Moet nie** die oordragnaald met filter gebruik om medisyne in te spuit nie, want dit kan moontlik skade soos pyn en bloeding veroorsaak.

---

**Herhaal stap A tot F met elke bykomende flessie totdat u meer as u voorgeskrewe dosis het. Sodra u klaar is, hou die oordragnaald met filter in die flessie en keer terug na stap 6. Gaan voort met die oorblywende stappe.**

### **Gebruiksaanwysings**

#### **Hemlibra®-inspuiting - Enkeldosisflessie(s)**

#### **OORDRAGNAALD**

#### **Opsie (om die Hemlibra van die flessie na die spuit oor te dra)**

U moet die instruksies vir gebruik lees, verstaan en volg voor u Hemlibra inspuit. U gesondheidsorgkundige moet u wys hoe om Hemlibra behoorlik voor te berei, af te meet en in te spuit voor u dit vir die eerste keer gebruik. Vra u gesondheidsorgkundige indien u enige vrae het.

#### **Belangrike inligting:**

- **Moenie** uself of iemand anders inspuit, tensy u deur u gesondheidsorgkundige gewys is hoe om dit te doen nie.
- Maak seker die naam Hemlibra verskyn op die boksie en flessie-etiket.
- Voor u die flessie oopmaak, lees die flessie-etiket om seker te maak u het die korrekte medisynesterkte(s) wat u benodig om die dosis toe te dien wat deur u gesondheidsorgkundige voorgeskryf is. Afhangende van u dosis moet u dalk meer as 1 flessie gebruik om u totale voorgeskrewe dosis toe te dien.

- Gaan die vervaldatum op die boksie en flessie-etiket na. Moenie gebruik indien die vervaldatum verby is nie.
- **Gebruik die flessie slegs een keer.** Nadat u u dosis ingespuut het, doen weg met (gooi weg) enige ongebruikte Hemlibra wat oor is in die flessie. Moenie ongebruikte medisyne in die flessie vir latere gebruik bêre nie.
- **Gebruik net die spuite, oordragnaalde, en inspuittingsnaalde wat u gesondheidsorgkundige voorskryf.**
- **Gebruik die spuite, oordragnaalde, en inspuittingsnaalde net een keer. Doen weg met (gooi weg) enige ongebruikte spuite en naalde.**
- Indien u voorgeskrewe dosis meer as 2 ml is, sal u meer as een (1) onderhuidse inspuiting Hemlibra moet kry; kontak u gesondheidsorgverskaffer vir die gepaste inspuittingsinstruksies.
- U moet Hemlibra slegs onder die vel inspuut.

#### **Hoe om Hemlibra-flessies, naalde en spuite te berg:**

- Hou die flessie in die oorspronklike boksie om die medisyne teen sonlig te beskerm.
- Hou die flessies, naalde en spuite buite die sig en bereik van kinders. Hou die flessie in die yskas.
- Moenie vries nie.
- Moenie die flessie skud nie.
- Haal die flessie 15 minute voor gebruik uit die yskas en laat dit kamertemperatuur bereik voor u 'n inspuiting voorberei.
- Sodra dit uit die yskas gehaal is, kan die onoopgemaakte flessie teen kamertemperatuur (onder 30 °C) vir tot 7 dae gehou word. Ná berging teen kamertemperatuur kan onoopgemaakte flessies terug in die yskas gesit word. Die totale hoeveelheid tyd buite die yskas en teen kamertemperatuur moet nie 7 dae oorskry nie.
- Gooi flessies weg wat vir langer as 7 dae teen kamertemperatuur gehou is, of wat in temperature bo 30 °C was.



- Hou die oordragnaald, inspuitingsnaald en -spuit droog.

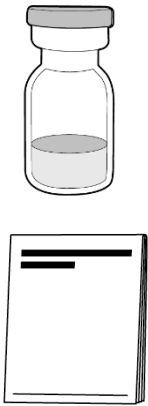
### Hoe om die medisyne en u benodighede na te gaan

- Maak alle benodighede wat hier onder gelys word, bymekaar om u inspuiting voor te berei en toe te dien.
- Gaan die vervaldatum op die boksie, op die flessie-etiket en op die benodighede wat hier onder gelys word, na. Moenie gebruik indien die vervaldatum verby is nie.

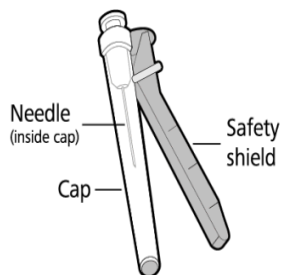
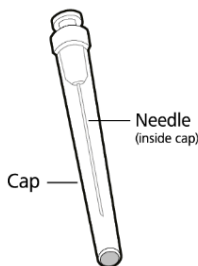
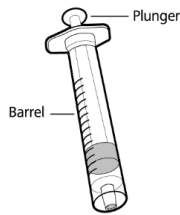
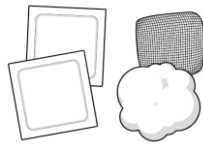
### Moenie die flessie gebruik indien:

- die medisyne troebel, wasig of verkleur is nie.
- die medisyne deeltjies bevat nie.
- die doppie wat die stopper bedek, weg is nie.
- Gaan die benodighede na vir skade. Moenie gebruik as dit beskadig lyk of as dit laat val is nie.
- Plaas die benodighede op 'n skoon, goed-beligte werksoppervlakte.

### INGESLUIT IN DIE BOKSIE:

	<ul style="list-style-type: none"><li>• Flessie wat die medisyne bevat</li> <li>• Gebruiksaanwysings vir Hemlibra</li></ul>
---	---

### NIE IN DIE BOKSIE NIE:



- **Alkohollappies**

**Let wel:** As u meer as 1 flessie moet gebruik om u voorgeskrewe dosis in te spuit, moet u 'n nuwe alkohollappie vir elke flessie gebruik.

- **Gaas**

- **Watteballetjie**

- **Spuit**

**Let wel:** Vir inspuitingshoeveelheid van tot 1 ml, gebruik 'n 1 ml-spuit.

Vir inspuitingshoeveelheid van tussen 1 ml en 2 ml, gebruik 'n 2 ml- of 3 ml-spuit.

- **18G-oordragnaald**

**Let wel:** As u meer as 1 flessie moet gebruik om u voorgeskrewe dosis in te spuit, moet u 'n nuwe oordragnaald vir elke flessie gebruik.

Moenie die oordragnaald gebruik om medisyne in te spuit nie.

- **26G-inspuitingsnaald met naaldveiligheidstoestel**

Moenie die inspuitingsnaald gebruik om medisyne uit die flessie te trek nie.

Weggooihouer vir skerppuntnaalde

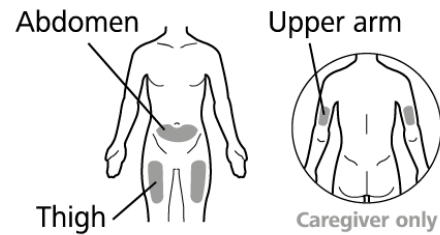
**Figuur A**

- Laat die flessie(s) toe om voor gebruik vir omtrent 15 minute kamertemperatuur te bereik op 'n skoon, plat oppervlakte weg van direkte sonlig.
- Moenie die flessie op enige ander manier probeer warm maak nie.
- Was u hande deeglik met seep en water.



### Hoe om 'n inspuittingsplek te kies en voor te berei:

- Maak die gekose inspuittingsplek met 'n alkohollappie skoon.
- Laat die vel vir omtrent 10 sekondes droog word. Moet nie voor u inspuiting aan die plek vat, dit droog waai of daarop blaas nie.



### U kan die volgende plekke vir u inspuiting gebruik:

- Dy (voor en middel).
- Maagarea (buik), behalwe vir 5 cm rondom die naeltjie.
- Buite op die boarm (slegs as 'n versorger die inspuiting gee).
- U moet elke keer wat u 'n inspuiting gee, 'n ander inspuittingsplek gebruik wat ten minste 2,5 cm weg is van die plek wat u vir u vorige inspuiting gebruik het.
- Moenie op plekke inspuit wat deur 'n gordel of broekband geïrriteer kan raak nie. Moenie in moesies, letsels, kneusplekke, of plekke waar die vel teer, rooi en hard of waar die vel stukkend is, inspuit nie.

### Hoe om die spuit vir inspuiting voor te berei

- Moenie aan die oop naalde raak of dit op 'n oppervlak sit nadat die doppie afgehaal is nie.
- Sodra die spuit met die medisyne gevul is, moet dit dadelik gebruik word.

- Sodra die inspuittingsnaald se doppie afgehaal is, moet die medisyne in die spuit binne 5 minute onder die vel ingespuut word. Moenie die spuit gebruik as die naald aan enige oppervlak raak nie.

### **Belangrike inligting ná die inspuiting**

- Moenie die inspuittingsplek ná 'n inspuiting vryf nie.
- As u druppels bloed by die inspuittingsplek sien, kan u 'n steriele watte of gaas vir ten minste 10 sekondes op die inspuittingsplek druk of totdat die bloeding gestop het.
- As u kneusing (klein area wat onder die vel bloei) het, kan 'n yspak ook liggies op die plek gedruk word. As bloeding nie stop nie, kontak asseblief u gesondheidsorgverskaffer.

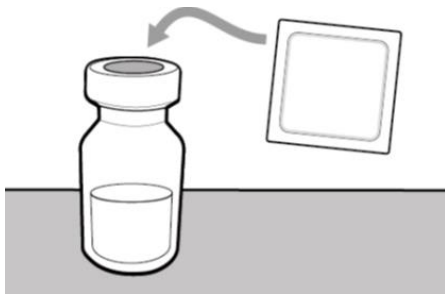
### **Wegdoening van die medisyne en benodighede:**

#### **Belangrik: Hou altyd die weggooihouer vir skerppuntnaalde buite bereik van kinders.**

- Gooi enige gebruikte flessie(s), naalde, flessie-/inspuittingsnaalddoppies en gebruikte spuite in 'n skerppuntnaald-/prikbestande houer.
- Sit u gebruikte naalde en spuite dadelik in 'n weggooihouer vir skerppuntnaalde ná gebruik. Moenie enige los naalde of spuite in u huishoudelike afval weggooi nie.
- Indien u nie 'n weggooihouer vir skerppuntnaalde het nie, kan u 'n houer in die huis gebruik wat:
  - van swardiensplastiek gemaak is.
  - kan toemaak met 'n deksel wat dig toemaak en prikbestand is sodat skerppuntnaalde nie kan uitval nie.
  - regop en stabiel gedurende gebruik is.
  - nie lek nie.
  - behoorlik gemerk is om te waarsku dat daar gevaarlike afval binne die houer is.
- Wanneer u weggooihouer vir skerppuntnaalde amper vol is, sal u u plaaslike riglyne moet volg vir die regte manier om u weggooihouer vir skerppuntnaalde weg te gooi.
- Moenie u weggooihouer vir skerppuntnaalde in u huishoudelike afval weggooi tensy u plaaslike riglyne dit toelaat nie. Moenie u gebruikte weggooihouer vir skerppuntnaalde herwin nie.

## 1. VOORBEREIDING

### Stap 1. Verwyder flessiedoppie en maak bokant skoon



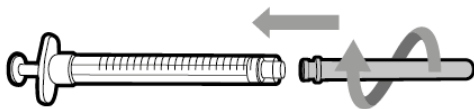
- Haal die doppie van die flessie(s) af.

- Maak die bokant van die flessie(s)-stopper met 'n alkohollappie skoon.

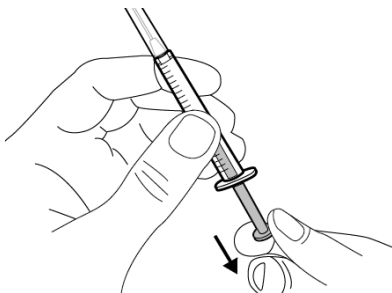
- Gooi die flessiedoppie(s) in die weggooihouer vir skerppuntnaalde.

- **Druk en draai die oordragnaald kloksgewys** op die spuit totdat dit heeltemal vas is.

### Stap 2. Sit 'n nuwe oordragnaald aan die spuit



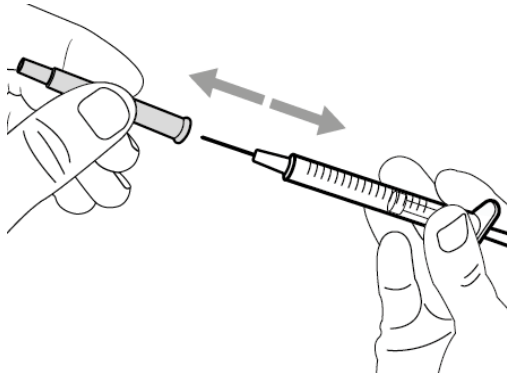
**Push and twist**



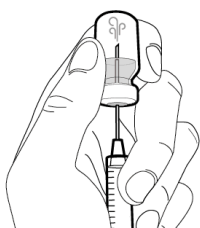
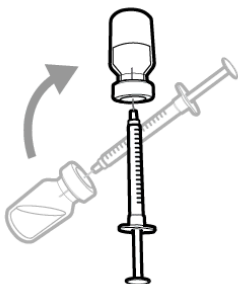
- Trek die suier stadig terug en trek dieselfde hoeveelheid lug in die spuit in vir u voorgeskrewe dosis.

- Hou die spuit aan die buis vas met die

### Stap 3. Haal doppie van oordragnaald af



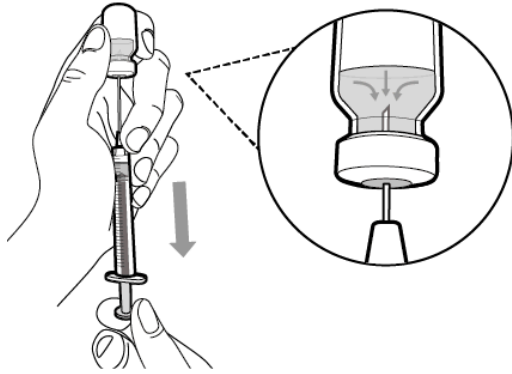
### Stap 4. Spuit lug in die flessie in



oordragnaald wat na bo wys.

- Trek die oordragnaaldoppie versigtig reguit en weg van u liggaam af. **Moenie die doppie weggooi nie. Plaas die oordragnaaldoppie op 'n plat oppervlak.** U sal die doppie weer op die oordragnaald moet terugsit nadat u die medisyne oorgedra het.
- **Moenie aan die naaldpunt raak** of dit op 'n oppervlak sit nadat die naaldoppie afgehaal is nie.
- Hou die flessie op die plat werksoppervlakte en druk die oordragnaald en -spuit reguit af in die middel van die flessiestopper in.
- Hou die naald in die flessie en draai die flessie onderstebo.
- Met die naald wat na bo wys, druk op die suier om die lug uit die spuitbo **die medisyne in te spuit.**
- Hou u vinger gedruk op die spuitsuier.
- **Moet nie** lug in die medisyne inspuit nie,

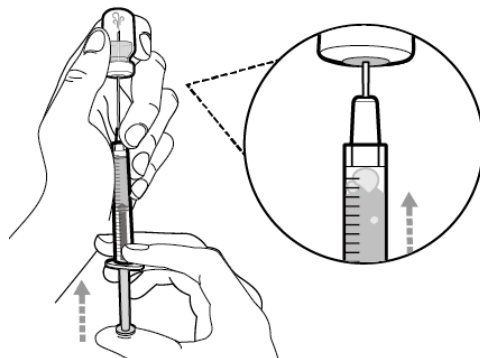
### Stap 5. Dra medisyne na spuit oor



- want dit kan lugborrels in die medisyne veroorsaak.
- Skuif die punt van die naald af sodat dit binne-in die medisyne is.
- Trek die suier stadig terug om die spuit te vul met meer as die hoeveelheid medisyne wat u vir u voorgeskrewe dosis benodig.
- Wees versigtig om nie die suier uit die spuit te trek nie.

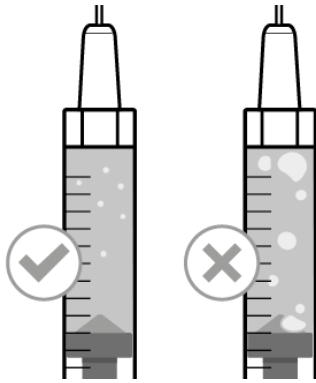
**Belangrik:** As u voorgeskrewe dosis meer as die hoeveelheid medisyne in die flessie is, **trek al die medisyne** uit en gaan nou na die **Hoe om flessies te kombineer**-afdeling.

### Stap 6. Verwyder lugborrels



- Hou die naald in die flessie en gaan die spuit vir groter lugborrels na. Te groot lugborrels kan die dosis verminder wat u ontvang.
- **Verwyder die groter lugborrels** deur liggies met u vingers aan die spuitbuis te tik totdat die lugborrels na die bokant van die spuit styg. Skuif die punt van die naald **na bo die medisyne** en druk die suier stadig na bo om die lugborrels uit die spuit te stoot
- As die hoeveelheid medisyne in die spuit nou by of onder u voorgeskrewe dosis is,





beweeg die punt van die naald **binne-in die medisyne** en trek die suier **stadig** terug tot u **meer** as die hoeveelheid medisyne het wat vir u **voorgeskrewe dosis** benodig word.

- Wees versigtig om nie die suier uit die spuit te trek nie.
- Herhaal die stappe hier bo totdat u die groter lugborrels verwyder het.

**Let wel:** Maak seker u het genoeg medisyne in die spuit om u dosis te voltooi voor u na die volgende stap gaan. As u nie al die medisyne kan verwyder nie, draai die flessie regop om die res daarvan te bereik.



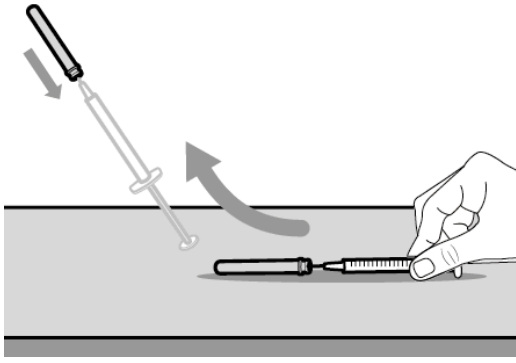
**Moet nie** die oordragnaald gebruik om medisyne in te spuit nie, want dit kan moontlik skade soos pyn en bloeding veroorsaak.

## 2. INSPUITING

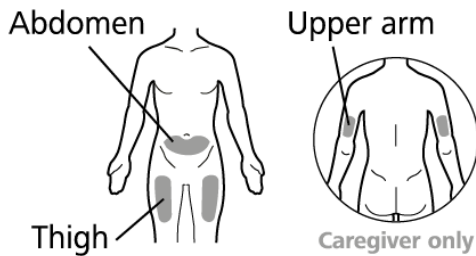
**Stap 7. Sit doppie terug op oordragnaald**

- Verwyder die spuit en oordragnaald uit die flessie.
- **Gebruik een hand om** die oordragnaald in die doppie in te skuif en **maak 'n skepbeweging na bo** om die naald te bedek.
- Sodra die naald bedek is, druk die oordragnaald doppie met **een hand** na die spuit om dit heeltemal op te sit om te voorkom dat u

u per ongeluk met die naald seermaak

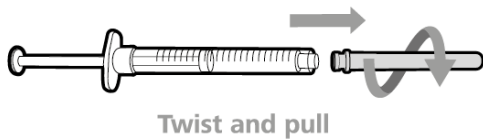


### Stap 8. Maak inspuitingsplek skoon



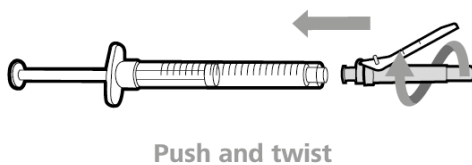
- Kies en maak u inspuitingsplek met 'n alkohollappie skoon.

### Stap 9. Verwyder oordragnaald



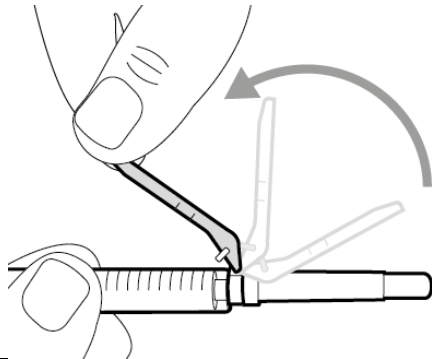
- Verwyder die oordragnaald uit die spuit deur dit antikloksgewys te draai en saggies te trek.
- Gooi die gebruikte oordragnaald in 'n weggooihouer vir skerppuntnaalde.

### Stap 10. Sit inspuitingsnaald vas aan die spuit



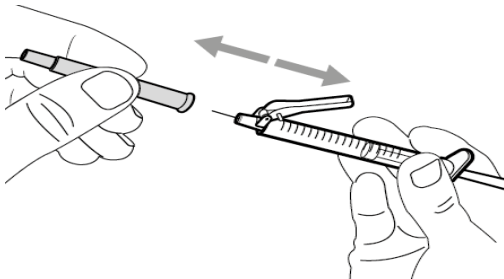
- Druk en draai die inspuitingsnaald kloksgewys op die spuit totdat dit heeltemal vassit.

### Stap 11. Skuif naaldveiligheidstoestel



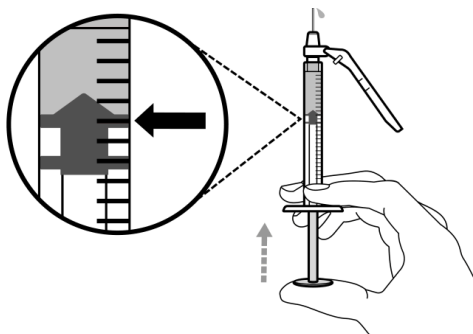
- Skuif die naaldveiligheidstoestel weg van die naald af en **na** die buis van die spuit toe.

### Stap 12. Haal doppie van inspuitingsnaald af



- Trek die inspuitingsnaalddoppie versigtig reguit weg van die spuit af.
- Gooi die doppie weg in 'n weggooi houer vir skerppuntnaalde
- **Moenie aan die naaldpunt raak** of dit aan enige oppervlakte laat raak nie.
- Sodra die inspuitingsnaald se doppie afgehaal is, moet die medisyne in die spuit binne 5 minute ingespuut word.

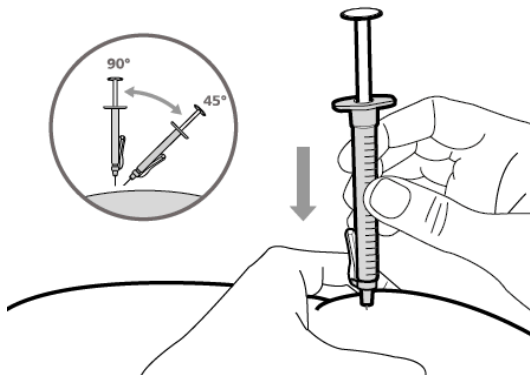
### Stap 13. Verstel suier na voorgeskrewe dosis



- Hou die spuit met die naald wat opwaarts wys en druk die suier stadig tot by u voorgeskrewe dosis.
- **Kontroleer u dosis** deur seker te maak die boonste rand van die suier is gelyk met die merk op die spuit vir u voorgeskrewe dosis.

### Stap 14. Onderhuidse (onder die vel) inspuiting

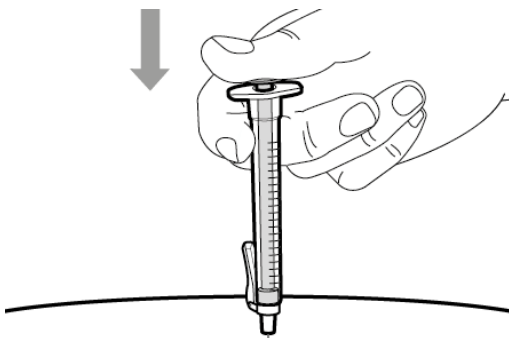
- Knyp die geselekteerde inspuitingsplek vas en steek die naald heeltemal teen 'n **45°- tot 90°-hoek** in met 'n vinnige, ferm aksie. **Moenie** die suier vashou of druk terwyl u die naald insteek



nie.

- Hou die posisie van die spuit en laat los die vasgeknypte inspuitingsplek.

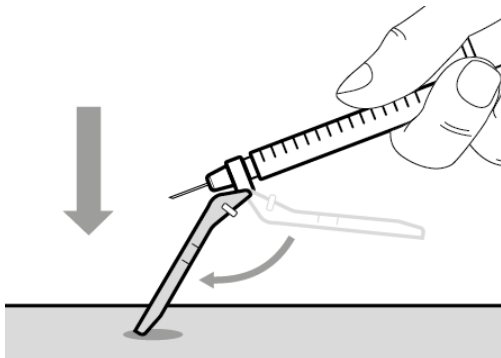
### Stap 15. Spuit die medisyne in



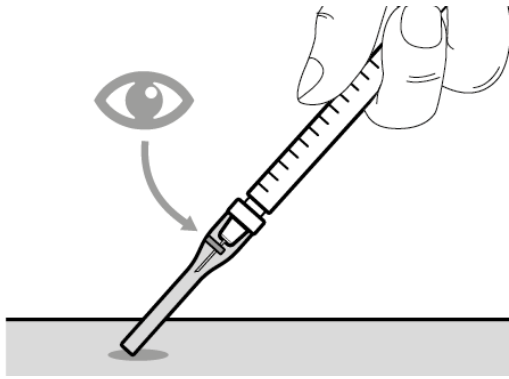
- Spuit al die medisyne stadig in deur die suier heeltetal af te druk.
- Haal die naald en spuit uit die inspuitingsplek teen dieselfde hoek as wat dit ingesteeek is.

## 3. WEGDOENING

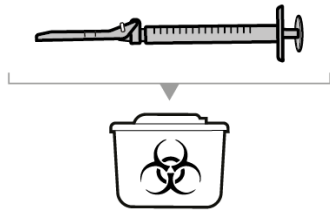
### Stap 16. Bedek naald met naaldveiligheidstoestel



- Skuif die naaldveiligheidstoestel 90° vorentoe, weg van die spuitbuis af.
- Terwyl u die spuit met een hand vashou, **druk die naaldveiligheidstoestel af** teen 'n plat oppervlakte met 'n ferm, vinnige aksie tot u 'n "klik" hoor.
- As u nie 'n klik hoor nie, kyk om te sien of die naald heeltetal deur die naaldveiligheidstoestel bedek word.



**Stap 17. Gooi die spuit en naald weg.**



- Hou u vingers altyd agter die naaldveiligheidstoestel en weg van die naald af.
- **Moet nie** die inspuitingsnaald losmaak nie
- Sit u gebruikte naalde en spuite in 'n weggooihouer vir skerppuntnaalde direk nadat u dit gebruik het. Vir verdere inligting, raadpleeg die afdeling "Wegdoening van die medisyne en benodighede".
- Moenie die gebruikte inspuitingsnaald van die gebruikte spuit probeer verwyder nie.
- Moenie die doppie weer op die inspuitingsnaald sit nie.
- Belangrik: Hou altyd die weggooihouer vir skerppuntnaalde buite bereik van kinders.
- Gooi enige gebruikte doppies, flessie(s), naalde en spuite in 'n skerppuntnaald- of prikbestande houer.

**Hoe om flessies te kombineer**

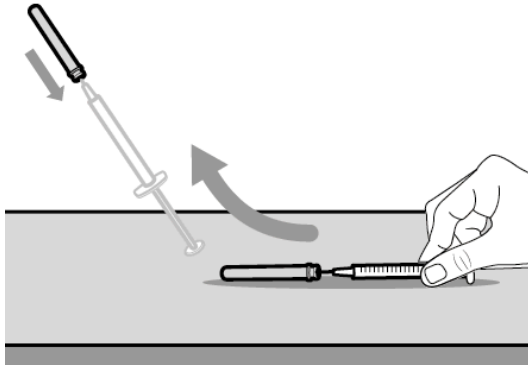
As u meer as 1 flessie benodig om u totale voorgeskrewe dosis te bereik, volg hierdie stappe nadat u die medisyne van die eerste flessie af opgetrek het:

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**Stap A. Sit doppie terug op**

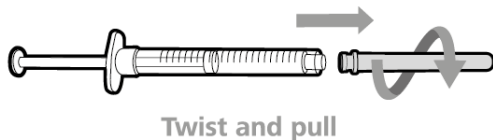
- Verwyder die spuit en oordragnaald uit die eerste flessie.
-

### **oordragnaald**



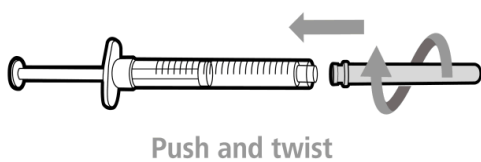
- **Gebruik een hand om die oordragnaald in die doppie in te skuif en maak 'n skepbeweging na bo** om die naald te bedek.
- Sodra die naald bedek is, druk die oordragnaalddoppie met een hand na die spuit om dit heeltemal op te sit om te voorkom dat u u per ongeluk met die naald beseer.

### **Stap B. Verwyder oordragnaald**



- Verwyder die oordragnaald uit die spuit deur dit antikloksgewys te draai en saggies te trek.
- Gooi die gebruikte oordragnaald in 'n weggooihouer vir skerppuntnaalde.

### **Stap C. Sit 'n nuwe oordragnaald aan die spuit**

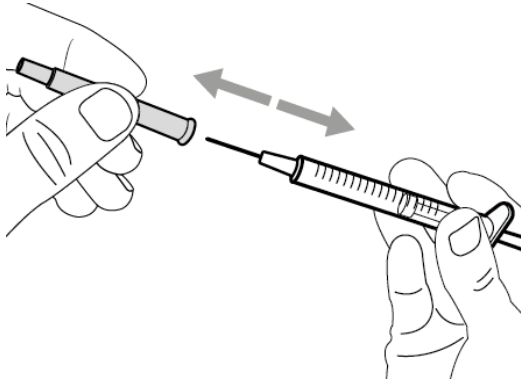


**Let wel: U moet elke keer 'n nuwe oordragnaald gebruik wanneer u medisyne uit 'n nuwe flessie optrek.**

- Druk en draai 'n **nuwe** oordragnaald kloksgewys op die spuit totdat dit heeltemal vas is.
- Trek die suier stadig terug en trek 'n bietjie lug in die spuit in.

### **Stap D. Haal doppie van oordragnaald af**

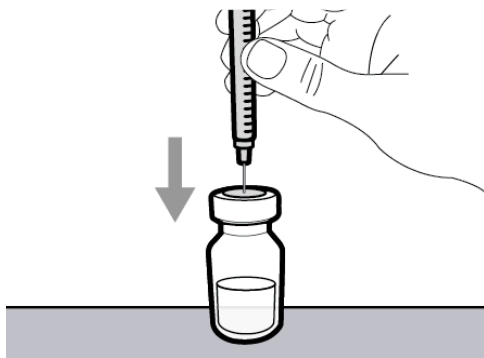
- Hou die spuit aan die buis vas met die oordragnaalddoppie wat na bo wys.
- Trek die oordragnaalddoppie versigtig reguit en weg van u liggaam af. Moenie die doppie weggooi nie. U sal die doppie weer op die



oordragnaald moet terugsit nadat u die medisyne opgetrek het.

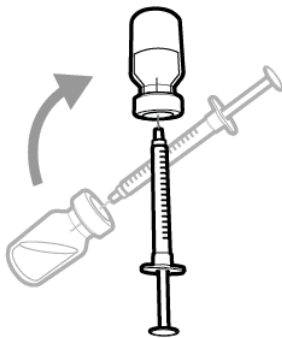
- Moenie aan die naaldpunt raak nie.

### Stap E. Spuit lug in die flessie in

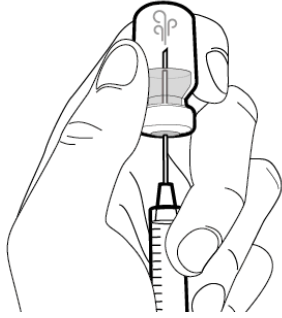


- Met die nuwe flessie op die plat werksoppervlakte, druk die oordragnaald en -spuit reguit af in die middel van die flessiestopper in.

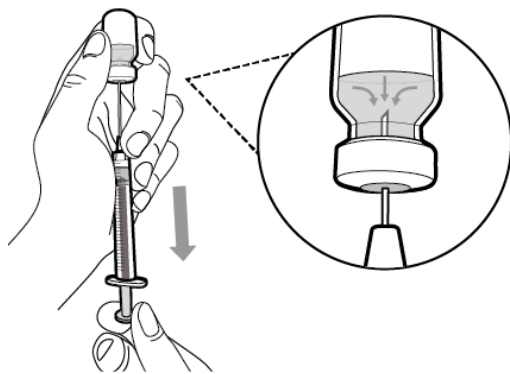
- Hou die oordragnaald in die flessie en draai die flessie onderstebo.



- Met die naald wat na bo wys, spuit die lug van die spuit af **bo die medisyne in**.
- Hou u vinger gedruk op die spuitsuier.
- Moet nie lug in die medisyne inspuit nie, want dit kan lugborrels in die medisyne veroorsaak.



### Stap F. Dra medisyne na spuit oor



- Skuif die punt van die naald af sodat dit **binne-in die medisyne** is.
- Trek stadig terug aan die suier om die spuitbuis te vul met meer as die hoeveelheid medisyne wat u vir u voorgeskrewe dosis benodig.
- Wees versigtig om nie die suier uit die spuit te trek nie.

**Let wel:** Maak seker u het genoeg medisyne in die spuit om u dosis te voltooi voor u na die volgende stap gaan. As u nie al die medisyne kan verwyder nie, draai die flessie regop om die res daarvan te bereik.



Moet nie die oordragnaald gebruik om medisyne in te spuit nie, want dit kan moontlik skade soos pyn en bloeding veroorsaak.

**Herhaal stap A tot F met elke bykomende flessie totdat u meer as u voorgeskrewe dosis het. Sodra u klaar is, hou die oordragnaald in die flessie en gaan terug na stap 6. Gaan voort met die oorblywende stappe.**





## Gebruiksaanwysings

### Hemlibra®-inspuiting - Enkeldosisflessie(s)

#### FLESSIEPASSTUK

Opsie (om die Hemlibra van die flessie na die spuit oor te dra)

U moet die instruksies vir gebruik lees, verstaan en volg voor u Hemlibra inspuit. U gesondheidsorgverskaffer moet u wys hoe om Hemlibra behoorlik voor te berei, af te meet en in te spuit voor u dit vir die eerste keer gebruik. Vra u gesondheidsorgverskaffer indien u enige vrae het.

#### Belangrike inligting:

Moet nie hierdie instruksies volg wanneer 'n oordragnaald gebruik word om Hemlibra uit die flessie te trek nie. Hierdie instruksies is slegs vir gebruik van die flessiepasstuk.

- **Moenie uself of iemand anders inspuit, tensy u deur u gesondheidsorgverskaffer gewys is hoe om dit te doen nie.**
- Maak seker die naam Hemlibra verskyn op die boksie en flessie-etiket.
- Voor u die flessie oopmaak, lees die flessie-etiket om seker te maak u het die korrekte medisynesterkte(s) om die dosis te gee wat vir u voorgeskryf is. U moet dalk meer as 1 flessie gebruik om uself die korrekte dosis te gee.
- Gaan die vervaldatum op die boksie en flessie-etiket na. **Moenie** gebruik indien die vervaldatum verby is nie.
- **Gebruik die flessie slegs een keer.** Nadat u u dosis ingespuit het, gooi enige ongebruikte Hemlibra wat oor is in die flessie weg. **Moenie** ongebruikte medisyne in die flessie vir latere gebruik bêre nie.
- **Gebruik net die spuite, flessiepasstukke en inspuitingsnaalde wat u gesondheidsorgverskaffer voorskryf.**

- **Gebruik die spuite, flessiepasstukke en inspuitingsnaalde net een keer. Gooi enige gebruikte doppies, flessie(s) en spuite weg.**
- Indien u voorgeskrewe dosis meer as 2 ml is, sal u meer as een onderhuidse inspuiting Hemlibra moet kry; kontak u gesondheidsorgverskaffer vir die inspuitingsinstruksies.
- U moet Hemlibra slegs onder die vel inspuit

#### **Hoe om Hemlibra-flessies, flessiepasstukke, naalde en spuite te berg:**

- Hou die flessie in die oorspronklike boksie om die medisyne teen sonlig te beskerm.
- Hou die flessies, flessiepasstukke, naalde en spuite buite die sig en bereik van kinders. Hou die flessie in die yskas.
- **Moenie** vries nie.
- **Moenie** die flessie skud nie.
- Haal die flessie 15 minute voor gebruik uit die yskas en laat dit kamertemperatuur (onder 30 °C) bereik voor u 'n inspuiting voorberei.

Sodra dit uit die yskas gehaal is, kan die onoopgemaakte flessie vir tot 7 dae teen kamertemperatuur gehou word. Ná berging teen kamertemperatuur kan onoopgemaakte flessies terug in die yskas gesit word. Die totale hoeveelheid tyd buite koelbewaring en teen kamertemperatuur moet nie 7 dae oorskry nie.



- Gooi flessies weg wat vir langer as 7 dae teen kamertemperatuur gehou is, of wat in temperature bo 30 °C was.
- Hou die flessiepasstuk, inspuitingsnaald en spuit droog.

#### **Hoe om die medisyne en u benodighede na te gaan:**

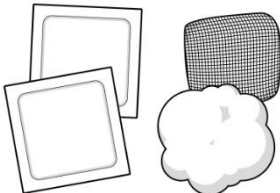
- Maak alle benodighede wat hier onder gelys word, bymekaar om u inspuiting voor te berei en toe te dien.
- **Kontroleer** die vervaldatum op die boksie, op die flessie-etiket en op die benodighede wat hier onder gelys word. **Moenie gebruik** indien die vervaldatum verby is nie.
- **Moenie die flessie gebruik** indien:

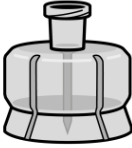
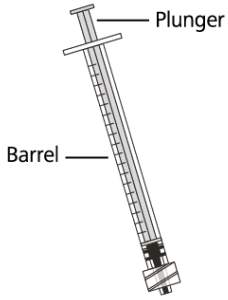
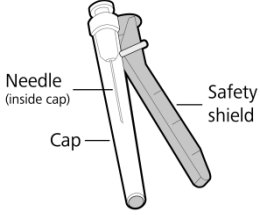

- die medisyne troebel, wasig of verkleur is nie.
- die medisyne deeltjies bevat nie.
- die doppie wat die stopper bedek, weg is nie.
- Gaan die benodighede na vir skade. **Moenie gebruik** as dit beskadig lyk of as dit laat val is nie.
- **Plaas die benodighede op 'n skoon, goed-beligte werksoppervlakte.**

**INGESLUIT IN DIE BOKSIE:**

	<ul style="list-style-type: none"><li>• <b>Flessie wat die medisyne bevat</b></li></ul>
	Gebruiksaanwysings <b>vir Hemlibra</b>

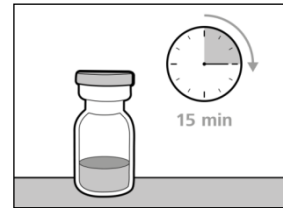
**NIE IN DIE BOKSIE NIE:**

	<ul style="list-style-type: none"><li>• <b>Alkohollappies</b> <b>Let wel:</b> As u meer as 1 flessie moet gebruik om u voorgeskrewe dosis in te spuit, moet u 'n nuwe alkohollappie vir elke flessie gebruik.</li><li>• <b>Gaas</b></li><li>• <b>Watteballetjie</b></li></ul>
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	<ul style="list-style-type: none"> <li>• <b>Flessiepasstuk</b> (Wat bo-op flessie gepas word).</li> </ul> <p><b>Let wel:</b> Word gebruik om medisyne uit die flessie in die spuit te trek. As u meer as 1 flessie moet gebruik om u voorgeskrewe dosis in te spuit, moet u 'n nuwe flessiepasstuk vir elke flessie gebruik.</p> <p><b>Insuitingsnaald in die flessiepasstuk indruk nie.</b></p>
	<ul style="list-style-type: none"> <li>• Spuit met kleindooiespasiesuier (Low Dead Space Plunger, LDS-suier)</li> </ul> <p>Belangrik:</p> <ul style="list-style-type: none"> <li>○ Vir inspuiting van tot 1 ml, gebruik 'n 1 ml- LDS-spuit.</li> <li>○ Vir inspuiting van meer as 1 ml, gebruik 'n 3 ml- LDS-spuit.</li> </ul> <p><b>Let wel:</b> Moenie 'n 3 ml- LDS-spuit vir dosisse van tot 1 ml gebruik nie.</p>
	<ul style="list-style-type: none"> <li>• <b>Inspuitingsnaald met naaldveiligheidstoestel</b> (word gebruik om medisyne in te spuit).</li> </ul> <p><b>Moet nie</b> die inspuitingsnaald in die flessiepasstuk druk of die inspuitingsnaald gebruik om medisyne uit die flessie te trek nie.</p>
	<ul style="list-style-type: none"> <li>• <b>Weggooihouer vir skerppuntnaalde</b></li> </ul>

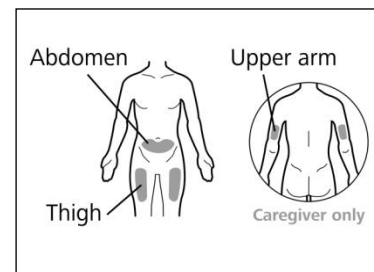
### Maak gereed:

- Laat die flessie(s) toe om voor gebruik vir omtrent 15 minute kamertemperatuur te bereik op 'n skoon, plat oppervlakte weg van direkte sonlig.
- **Moenie** die flessie op enige ander manier probeer warm maak nie.
- Was u hande **deeglik met seep en water**.



### Hoe om 'n inspuitingsplek te kies en voor te berei:

- Maak die gekose inspuitingsplek met 'n alkohollappie skoon.
- Laat die vel vir omtrent 10 sekondes droog word.  
**Moet nie** voor u inspuiting aan die plek vat, dit droog waai of daarop blaas nie.



### U kan die volgende plekke vir u inspuiting gebruik:

- Dy (voor en middel).
- Maagarea (buik), behalwe vir 5 cm rondom die naeltjie.
- Buite op die boarm (slegs as 'n versorger die inspuiting gee).
- U moet 'n ander inspuitingsplek gebruik vir elke inspuiting wat ten minste 2,5 cm weg is van die plek wat u vir u vorige inspuiting gebruik het.
- Moenie op plekke inspuit wat deur 'n gordel of broekband geïrriteer kan raak nie. Moenie in moesies, letsels, kneusplekke, of plekke waar die vel teer, rooi en hard of waar die vel stukkend is, inspuit nie.

### Vorbereiding van die spuit vir inspuiting:

- Moenie aan die oop naalde raak of dit op 'n oppervlak sit nadat die doppe afgehaal is nie.
- Sodra die spuit met die medisyne gevul is, moet die inspuiting dadelik gegee word.

- Sodra die inspuittingsnaald se doppie afgehaal is, moet die medisyne in die spuit binne 5 minute onder die vel ingespuit word. Moenie die spuit gebruik as die naald aan enige oppervlak raak nie

#### **Belangrike inligting ná die inspuiting:**

- Moenie die inspuittingsplek ná inspuiting vryf nie.
- **As u druppels bloed by die inspuittingsplek sien, kan u 'n steriele watte of gaas vir ten minste 10 sekondes op die inspuittingsplek druk of totdat die bloeding gestop het.**
- As u kneusing (klein area wat onder die vel bloei) het, kan 'n yspak ook liggies op die plek gedruk word. As bloeding nie stop nie, kontak asseblief u gesondheidsorgverskaffer.

#### **Wegdoening van die medisyne en benodighede:**

##### **Belangrik: Hou altyd die weggooihouer vir skerppuntnaalde buite bereik van kinders.**

- **Gooi enige gebruikte doppies, flessie(s), flessiepasstukke, naalde en spuite in 'n skerppuntnaalde- of prikbestande houer.**
- Sit u gebruikte flessiepasstukke, naalde en spuite dadelik in 'n weggooihouer vir skerppuntnaalde ná gebruik. Moenie enige los doppies, flessies, naalde en spuite in u huishoudelike afval weggooi nie.
- Indien u nie 'n weggooihouer vir skerppuntnaalde het nie, kan u 'n houer in die huis gebruik wat:
  - van swaardiensplastiek gemaak is.
  - kan toemaak met 'n deksel wat dig toemaak en prikbestand is sodat skerppuntnaalde nie kan uitval nie.
  - regop en stabiel gedurende gebruik is.
  - nie lek nie.
  - behoorlik gemerk is om te waarsku dat daar gevaarlike afval binne die houer is.
- Wanneer u weggooihouer vir skerppuntnaalde amper vol is, sal u u plaaslike riglyne moet volg vir die regte manier om u weggooihouer vir skerppuntnaalde weg te gooi.

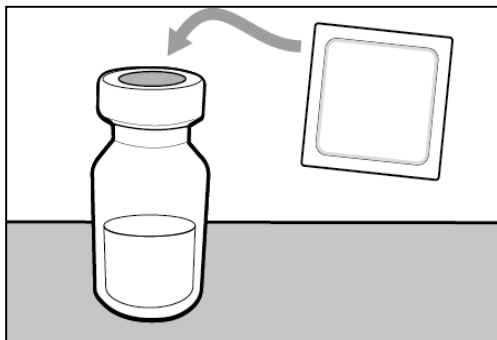
- Moenie u weggoi houer vir skerppuntnaalde in u huishoudelike afval weggooi tensy u plaaslike riglyne dit toelaat nie. Moenie u gebruikte weggoi houer vir skerppuntnaalde herwin nie.

## 1. VOORBEREIDING

### Stap 1. Verwyder flessiedoppie en maak bokant skoon



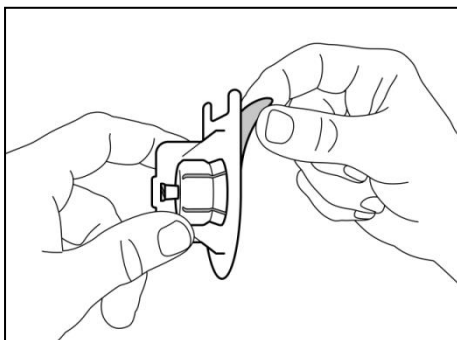
- Haal die doppie van die flessie(s) af.
- Gooi die flessiedoppie(s) in die weggoi houer vir skerppuntnaalde.



- Maak die bokant van die flessie(s)-stopper met 'n alkohollappie skoon.

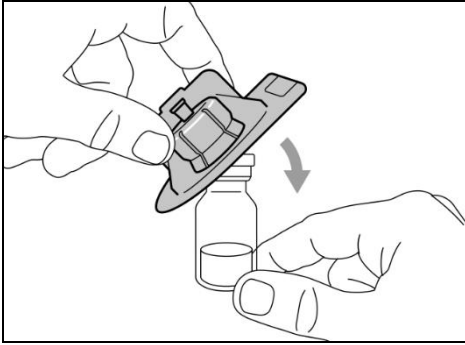
### Stap 2. Druk flessiepasstuk bo-op

#### die flessie

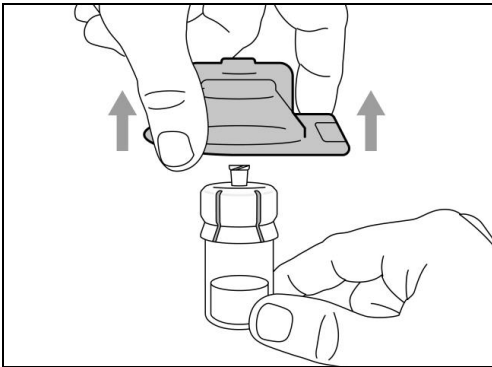


- Trek die agterkant af om die stulppak oop te maak.

**⚠ Moet nie die flessiepasstuk uit die deursigtige plastiek stulppak haal nie.**

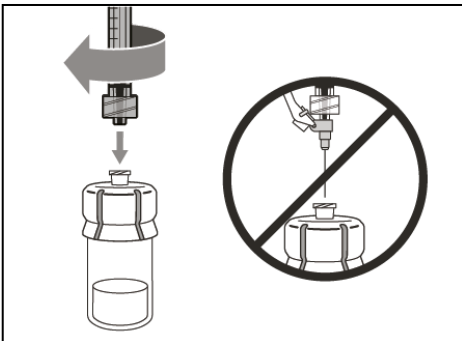


- Druk die plastiek stulppak met die flessiepasstuk ferm teen 'n hoek bo-op die nuwe flessie af totdat u 'n “**klied**” hoor.



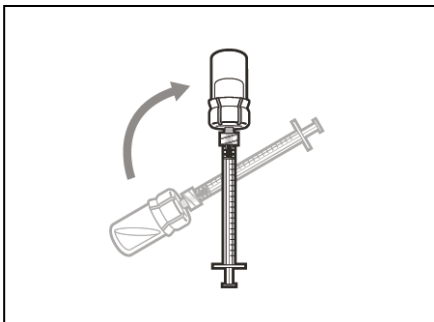
- Haal die plastiek stulppak af en gooi dit weg.
- **Moet nie** aan die punt van die flessiepasstuk raak nie.

### Stap 3. Verbind spuit met flessiepasstuk



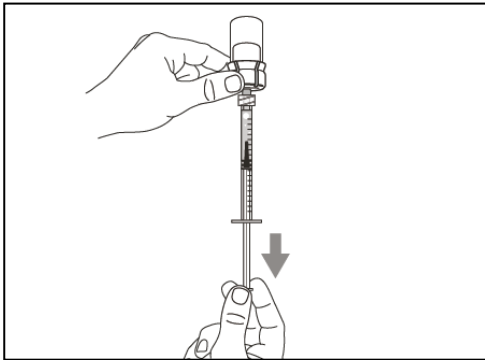
- **Haal spuitdoppe af** (indien nodig).
- **Druk en draai die spuit kloksgewys** op die flessiepasstuk totdat dit heeltemal vas is.

### Stap 4. Dra medisyne na spuit oor



- Hou die flessiepasstuk aan die spuit en draai die flessie onderstebo.

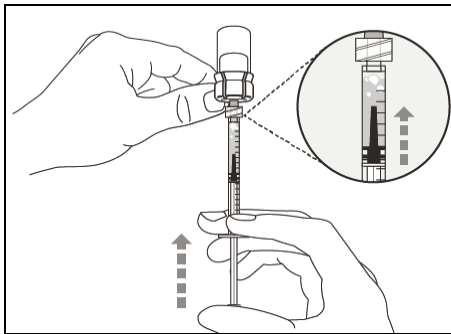




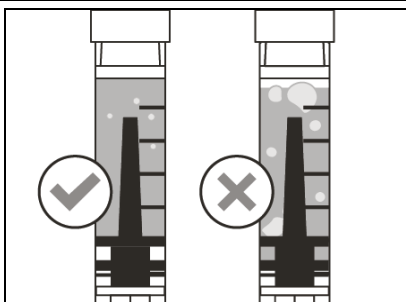
- Met die spuit wat na bo wys, trek die suier stadig terug om die **spuit te vul met** meer as die hoeveelheid **medisyne** wat u vir u voorgeskrewe dosis benodig.
- **Hou die suier ferm vas** om seker te maak dat dit nie terug in trek nie.
- Wees versigtig om nie die suier uit die spuit te trek nie.

**Belangrik:** As u voorgeskrewe dosis meer as die hoeveelheid Hemlibra in die flessie is, **trek al die medisyne** uit en gaan nou na die “**Hoe om flessies te kombineer**”-afdeling

#### Stap 5. Verwyder lugborrels



- Hou die naald in die flessie en **gaan die spuit vir groter lugborrels na**. Groot lugborrels kan die dosis verminder wat u ontvang.



- **Verwyder die groter lugborrels** deur liggies met u vingers aan die spuitbuis te **tik** totdat die lugborrels na die bokant van die spuit styg. **Druk die suier stadig** om die groot lugborrels uit die spuit te druk.
- As die hoeveelheid medisyne in die spuit nou by of onder u voorgeskrewe dosis is, trek die suier stadig terug tot u **meer** as die hoeveelheid medisyne het wat vir u **voorgeskrewe dosis** benodig word.
- Wees versigtig om nie die suier uit die spuit te trek

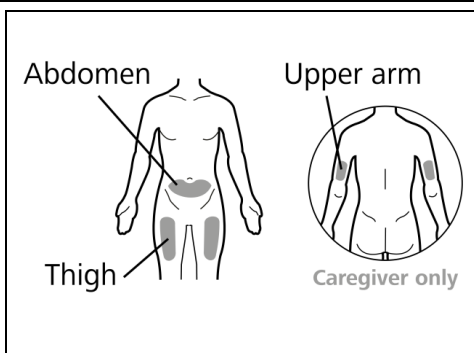
nie.

- Herhaal die stappe hierbo totdat u die groter lugborrels verwyder het.

**Let wel:** Maak seker u het genoeg medisyne in die spuit om u dosis te voltooi voor u na die volgende stap gaan.

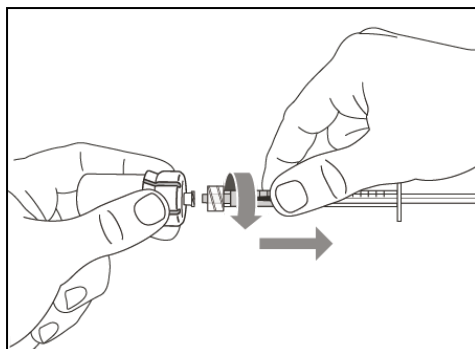
## 2. INSPUITING

### Stap 6. Maak inspuitingsplek skoon



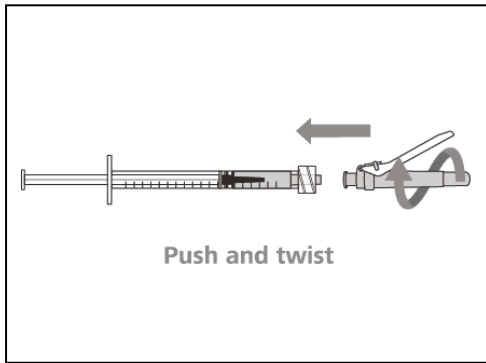
- Kies en maak u inspuitingsplek met 'n alkohollappie **skoon**.

### Stap 7. Haal die spuit uit die flessiepasstuk



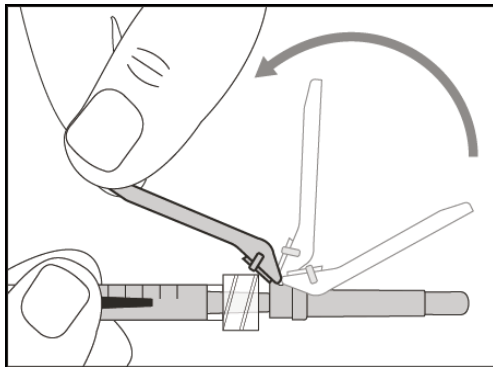
- Haal die spuit uit die flessiepasstuk deur dit antikloksgewys te draai en saggies te trek.
- Gooi die gebruikte flessie/flessiepasstuk weg in 'n weggooihouer vir skerppuntnaalde.

### Stap 8. Sit inspuitingsnaald vas aan die spuit



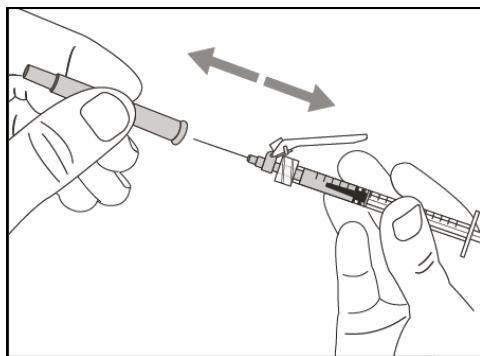
- Druk en draai die inspuitingsnaald kloksgewys op die spuit totdat dit heeltetal vassit.
- **Moet nie** die inspuitingsnaald in die flessiepasstuk druk of die inspuitingsnaald gebruik om medisyne uit die flessie te trek nie.

### Stap 9. Skuif naaldveiligheidstoestel



- Skuif die naaldveiligheidstoestel weg van die naald af en na die buis van die spuit.

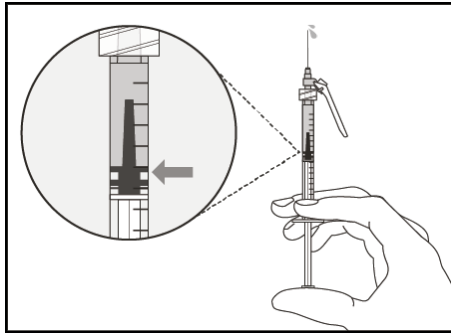
### Stap 10. Haal doppie van inspuitingsnaald af



- **Trek** die inspuitingsnaalddoppie **versigtig reguit** weg van die spuit af.
- Gooi die doppie weg in 'n weggooi houer vir skerppuntnaalde.
- **Moenie aan die naaldpunt raak** of dit aan enige oppervlakte laat raak nie.
- Sodra die inspuitingsnaald se doppie afgehaal is, moet die medisyne in die spuit binne 5 minute ingespuit word.

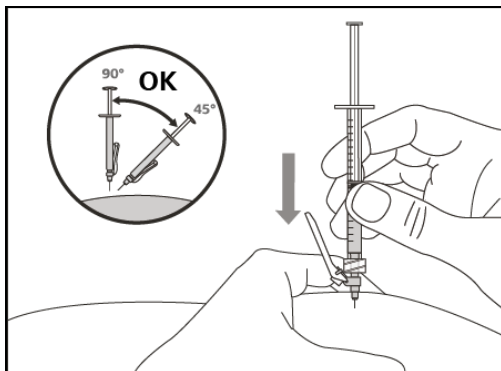
### Stap 11. Verstel suier na voorgeskrewe dosis

- Hou die spuit met die naald wat opwaarts wys en druk die suier stadig tot by u voorgeskrewe dosis.
- **Kontroleer u dosis** deur seker te maak die



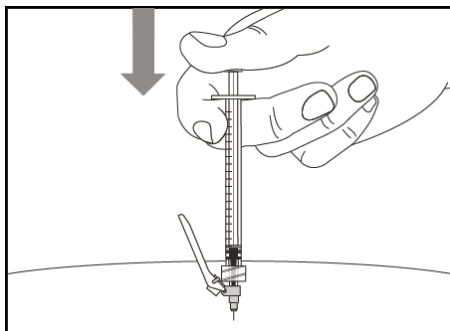
boonste rand van die suier is gelyk met die merk op die spuit vir u voorgeskrewe dosis.

### Stap 12. Onderhuidse (onder die vel) inspuiting



- Knyp die geselekteerde inspuitingsplek vas en steek die naald heeltemal teen 'n **45°-tot 90°**-hoek in met 'n vinnige, ferm aksie. **Moenie** die suier vashou of druk terwyl u die naald insteek nie.
- Hou die posisie van die spuit en laat los die vasgeknypte inspuitingsplek.

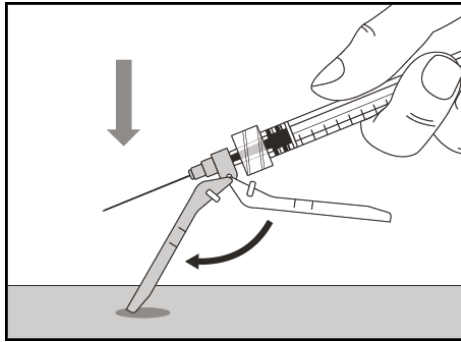
### Stap 13. Spuit die medisyne in



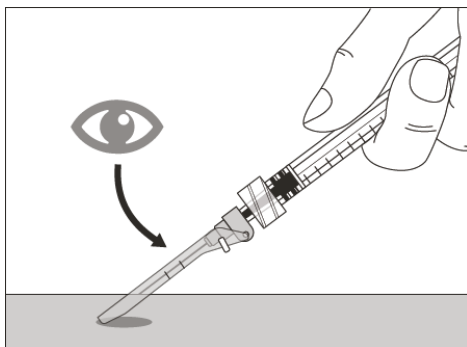
- Spuit al die medisyne in deur die suier saggies heeltemal af te druk.
- Haal die naald en spuit uit die inspuitingsplek teen dieselfde hoek as wat dit ingestek is.

## 3. WEGDOENING

### Stap 14. Bedek naald met naaldveiligheidstoestel

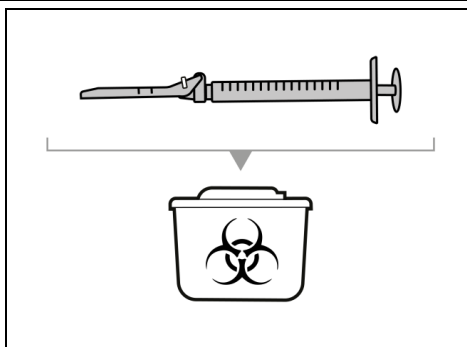


- Skuif die naaldveiligheidstoestel 90° vorentoe, weg van die spuitbuis af.
- **Terwyl u die spuit met een hand vashou, druk die naaldveiligheidstoestel af** teen 'n plat oppervlakte met 'n ferm, vinnige aksie tot u 'n "klik" hoor.



- As u nie 'n klik hoor nie, kyk om te sien of die naald heeltemal deur die naaldveiligheidstoestel bedek word.
- Hou u vingers altyd agter die naaldveiligheidstoestel en weg van die naald af.
- **Moet nie** die inspuitingsnaald losmaak nie.

### Stap 15. Gooi die naald en spuit weg



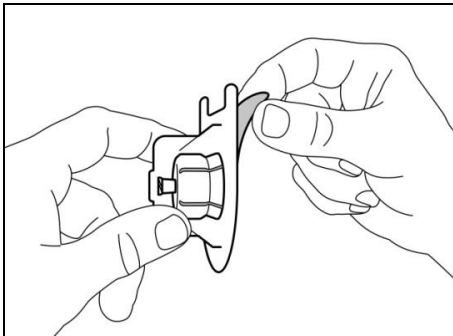
- Sit u gebruikte naalde en spuite in 'n weggooihouer vir skerppuntnaalde direk nadat u dit gebruik het. Vir verdere inligting, raadpleeg die afdeling "Wegdoening van die medisyne en benodighede".
- **Moenie** die gebruikte inspuitingsnaald van die gebruikte spuit probeer verwyder nie.
- **Moenie** die **doppie weer** op die inspuitingsnaald sit nie.
- **Belangrik:** Hou altyd die weggooihouer vir skerppuntnaalde buite bereik van kinders.
- Gooi enige gebruikte doppies, flessie(s), flessiepasstukke, naalde en spuite in 'n

skerppuntnaalde- of prikbestande houer.

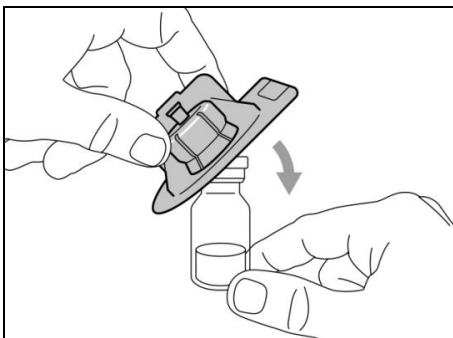
### Hoe om flessies te kombineer

As u meer as 1 flessie benodig om u voorgeskrewe dosis te bereik, volg hierdie stappe nadat u die medisyne van die eerste flessie af opgetrek het:

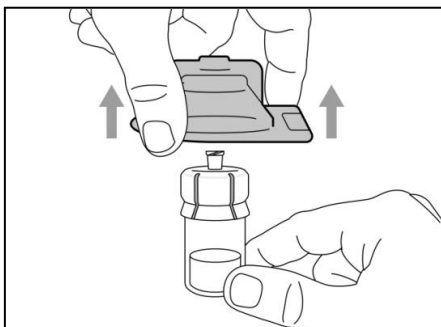
#### Stap A. Sit 'n nuwe flessiepasstuk op die flessie



- Trek die agterkant af om die stulppak oop te maak.
- ⚠ **Moet nie die flessiepasstuk uit die deursigtige plastiek stulppak haal nie.**

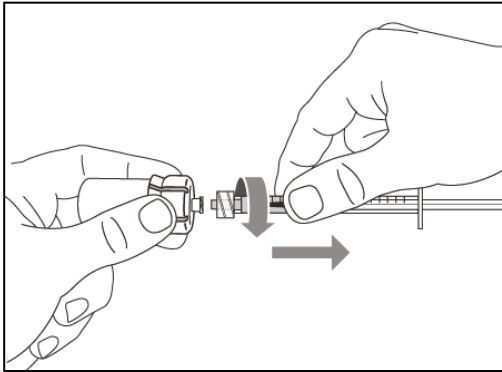


- Druk die plastiek stulppak met die flessiepasstuk ferm teen 'n hoek bo-op die nuwe flessie af totdat u 'n **'kliek'** hoor.



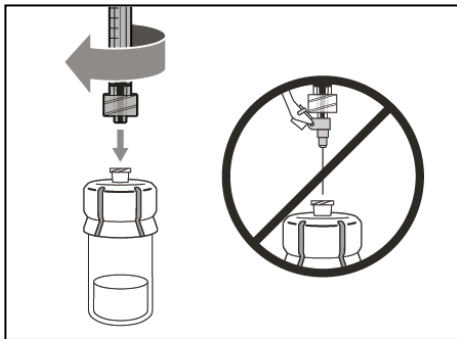
- Haal die plastiek stulppak af en gooi dit weg.
- **Moet nie** aan die punt van die flessiepasstuk raak nie.

### Stap B. Haal die flessiepasstuk af



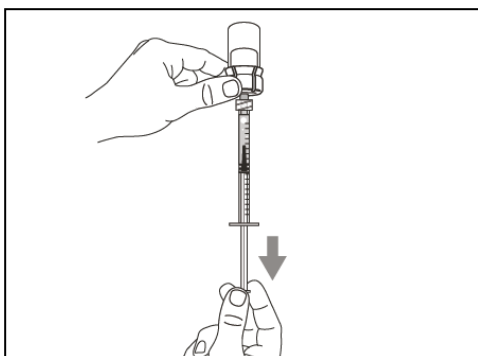
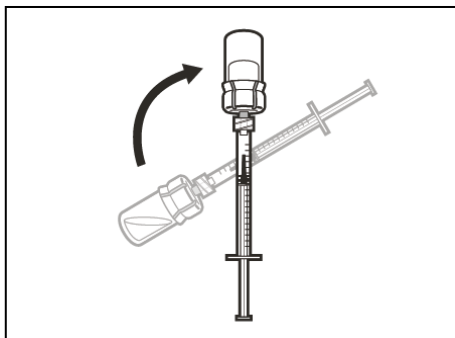
- Haal die gebruikte flessiepasstuk van die spuit deur dit antiklokgewys te draai en saggies te trek.
- Gooi die gebruikte flessie/flessiepasstuk weg in 'n weggooihouer vir skerppuntnaalde.

### Stap C. Verbind nuwe flessiepasstuk met spuit



- **Druk en draai die spuit klokgewys** op die flessiepasstuk totdat dit heeltemal vas is.

### Stap D. Dra medisyne na spuit oor



- Hou die flessiepasstuk aan die spuit en draai die flessie onderstebo.
- Met die spuit wat na bo wys, trek die suier stadig terug om die **spuit te vul met** meer as die hoeveelheid **medisyne** wat u vir u voorgeskrewe dosis benodig.
- **Hou die suier ferm** vas om seker te maak dat dit nie terug in trek nie.



- Wees versigtig om nie die suier uit die spuit te trek nie.

**Let wel:** Maak seker u het genoeg medisyne in die spuit om u dosis te voltooi voor u na die volgende stap gaan.

**Herhaal stap A tot D met elke bykomende flessie totdat u meer as die hoeveelheid medisyne het as wat vir u voorgeskrewe dosis nodig is. Sodra u klaar is, hou die flessiepasstuk op die flessie en gaan terug na Stap 5 “Verwyder lugborrels”. Gaan voort met die oorblywende stappe.**