# 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

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

**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**

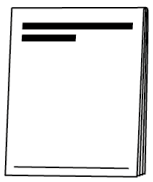
- Collect all supplies listed below to prepare and give your injection.
- **Check** the expiry date on the box, on the vial label and on the supplies listed below. **Do not use** if the expiry date has passed.
-

**Do not use** the vial if**:**

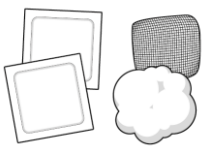
- the medicine is cloudy, hazy or coloured.
- the medicine contains particles.
- the cap covering the stopper is missing.

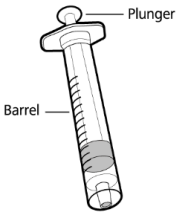
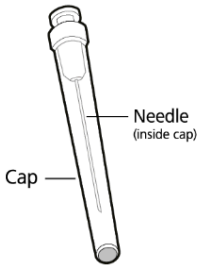
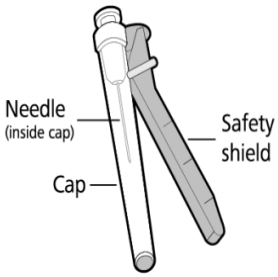
- Inspect the supplies for damage. **Do not use** if they appear damaged or if they have been dropped.
- Place the supplies on a clean, well-lit flat work surface.

**INCLUDED IN THE BOX:**

| | |
|---|---|
| | • **Vial containing the medicine** |
|  | • Hemlibra **Instructions for Use** |

**NOT INCLUDED IN THE BOX:**

| | |
|---|---|
|  | • **Alcohol wipes**<br>**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.<br>• **Gauze**<br>• **Cotton Ball** |

| | |
|---|---|
|  <br>  <br>  <br> | • **Syringe**<br><br>**Note:** For injection amount up to 1 mL use a **1 mL syringe.**<br><br>For injection amount between 1mL and 2 mL use a **2 mL or 3 mL syringe**.<br><br>• **18G Transfer Needle with 5 micrometer filter**<br><br>**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.<br><br>**Do not** use the transfer needle with filter to inject medicine.<br><br>• **26G Injection Needle with safety shield**<br><br>**Do not** use the injection needle to withdraw medicine from vial.<br><br>**Sharps disposal container** |

- 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.

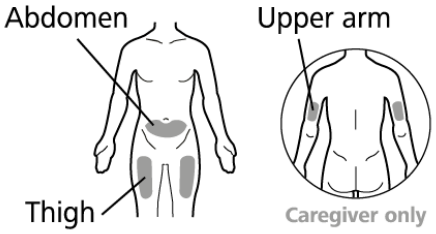



**Figure B**

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.

**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 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:**

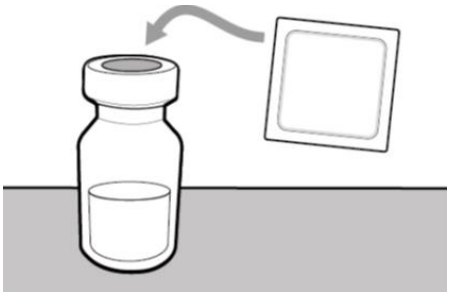
**Important: Always keep the sharps disposal container out of reach of children.**

- 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

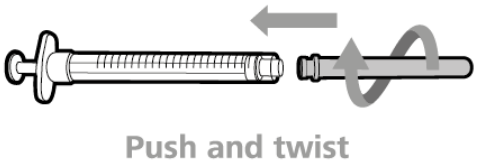
**Step 1. Remove vial cap and clean top**

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

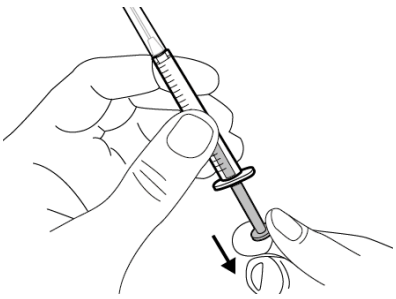


- Clean the top of the vial(s) stopper with an alcohol wipe.

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

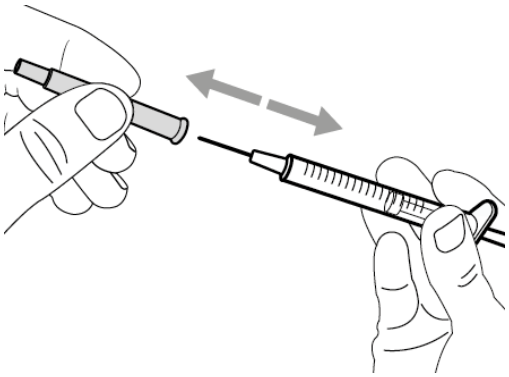



- **Push and twist the transfer needle with filter clockwise** on to the syringe until it is fully attached.



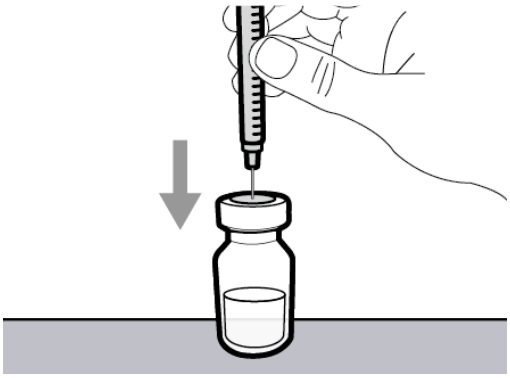
- Slowly pull back on the plunger and draw air into the syringe that is the same amount as your prescribed dose.

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

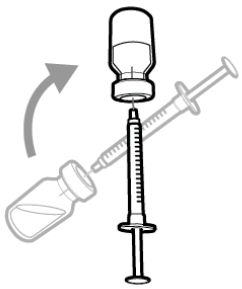


- Hold the syringe by the barrel with the transfer needle with filter pointing up.
- Carefully pull the transfer needle with filter cap straight off and away from your body. **Do not throw the cap away. Place the transfer needle with filter cap down on a clean flat surface.** You will need to recap the 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.

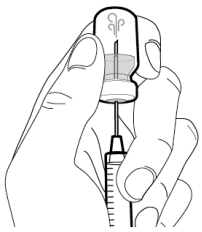
**Step 4. Inject air into vial**



- 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.

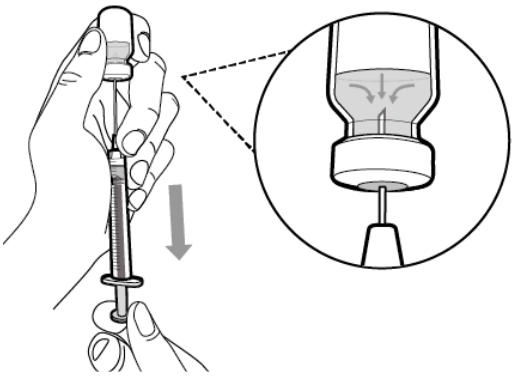


- Keep the needle in the vial and turn the vial upside down.



- 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**



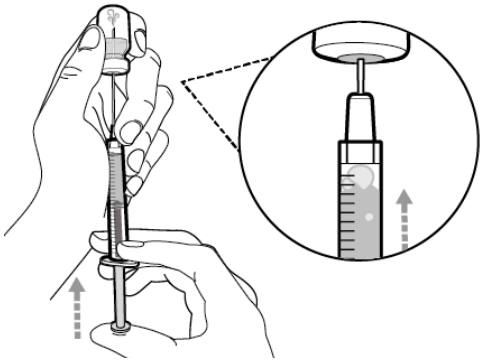
- Slide the tip of the needle down so that it is **within the medicine.**
- **Slowly** pull back the plunger to prevent air bubbles/foam.

  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.

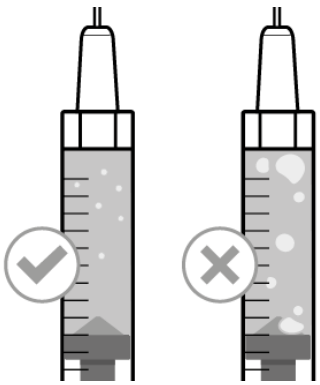
**Step 6. Remove air bubbles**

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



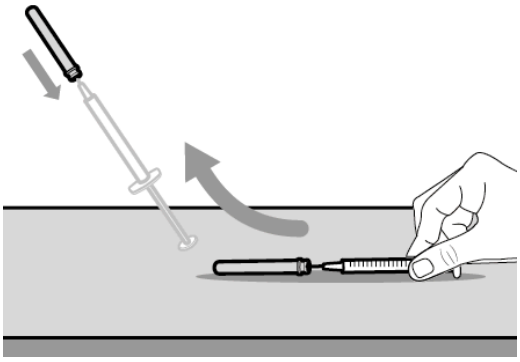
**Note:** Ensure you have enough medicine in the syringe to complete your dose before moving onto the next step. If you cannot remove all medicine, turn the vial upright to reach the remaining amount.

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

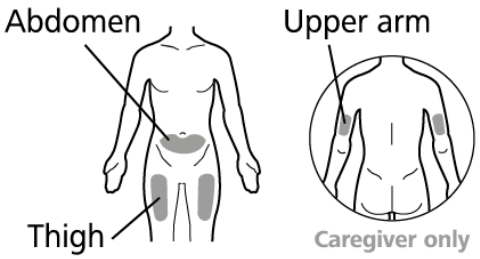
bleeding.

**2. INJECTION**

**Step 7. Recap transfer needle with filter**



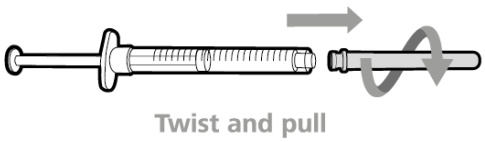
4. Remove the syringe and transfer needle with filter from the vial.
5. **Using one hand, slide** the transfer needle with filter into the cap and **scoop upwards** to cover the needle.
6. Once the needle is covered, push the transfer needle with filter cap towards the syringe to fully attach it with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




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

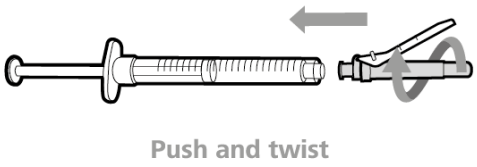
**Step 8. Clean injection site**

**Step 9. Remove transfer needle with filter**

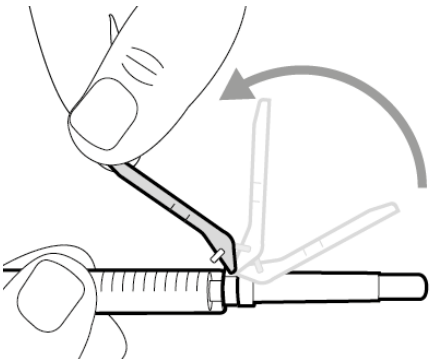



- Remove the transfer needle with filter from the syringe by twisting anticlockwise and gently pulling.
- Throw away the used transfer needle with filter into a sharps disposal container.

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



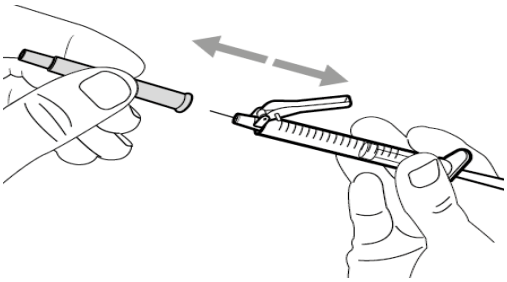

- Push and twist the injection needle clockwise onto the syringe until it is fully attached.



**Step 11. Move safety shield**

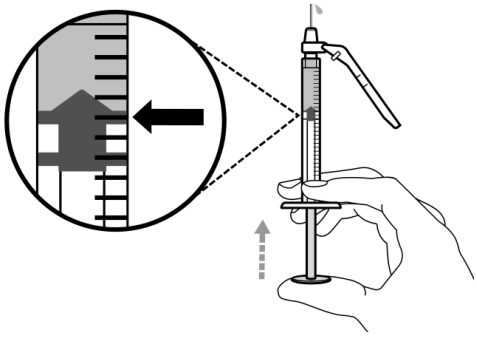
- Move the safety shield away from the needle and **towards** the syringe barrel.

**Step 12. Uncap injection needle**



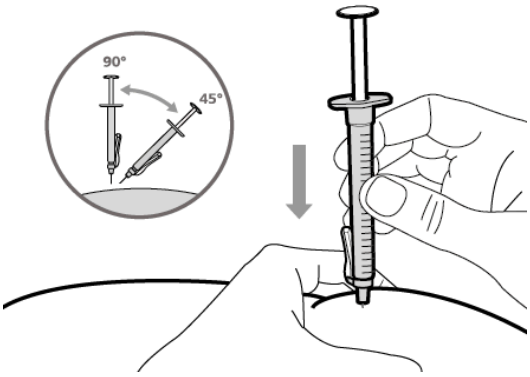
- **Carefully** pull the injection needle cap straightaway from the syringe.
- Throw away the cap into a sharps disposal container.
- **Do not touch** the needle tip or allow it to touch any surface.
- After the injection needle cap has been removed, the medicine in the syringe must be injected within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

**Step 13. Adjust plunger to prescribed dose**



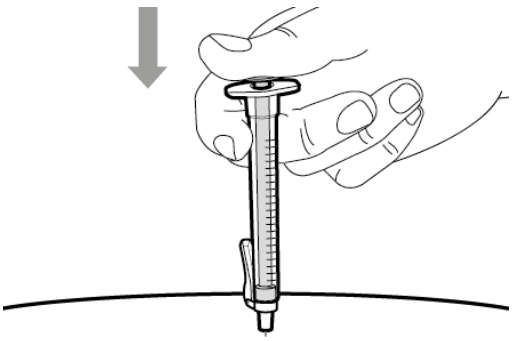
- Hold the syringe with the needle pointing up and slowly push the plunger to your prescribed dose.
- **Check your dose,** ensure the top rim of the plunger is in line with the mark on the syringe for your prescribed dose.

**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.

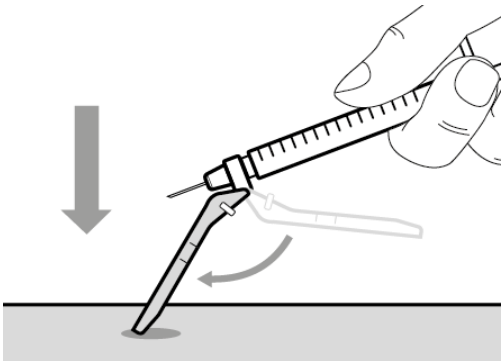
**Step 15. Inject the medicine**



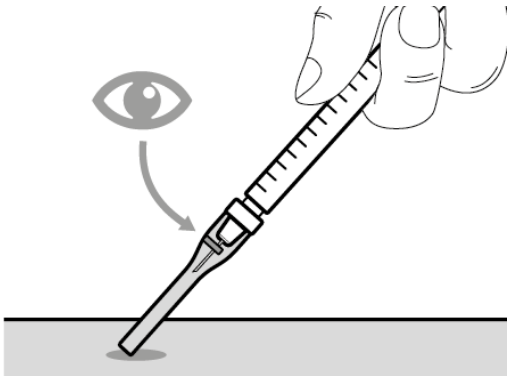
- Slowly inject all of the medicine by gently pushing the plunger all the way down.
- Remove the needle and syringe from the injection site at the same angle as inserted.

### 3. DISPOSAL

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

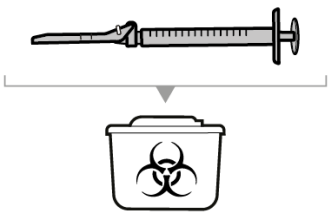


- Move the safety shield forward 90°, away from the syringe barrel.
- Holding the syringe with one hand, **press the safety shield down** against a flat surface with a firm, quick motion until you hear a "click".



- 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. 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

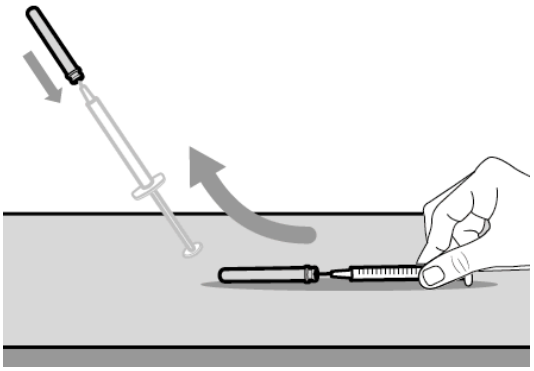
container out of reach of children.

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

**Combining Vials**

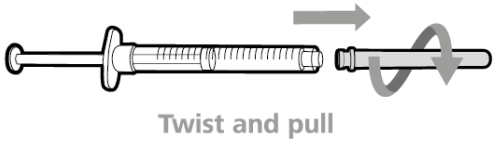
If you need to use more than 1 vial to get to your prescribed dose, follow these steps after you have drawn up the medicine from the first vial:

**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.

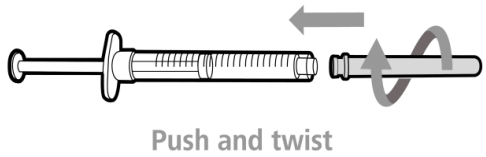
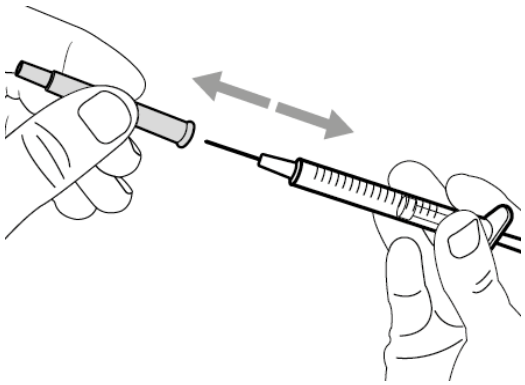
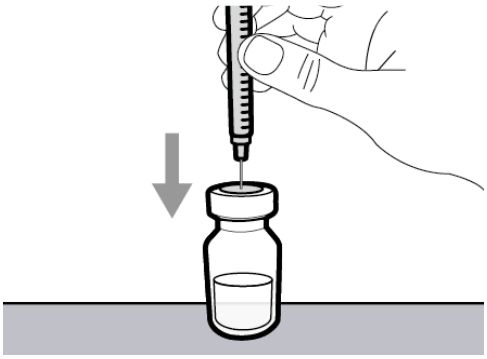
**Step B. Remove transfer needle with filter**

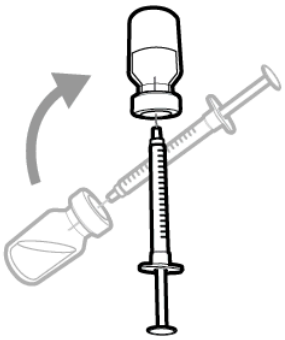


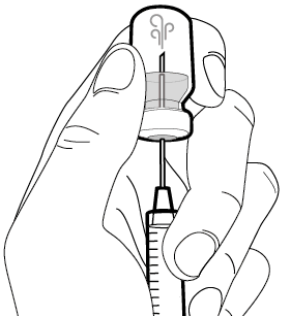

- Remove the transfer needle with filter from the syringe by twisting anticlockwise and gently pulling.
- Throw away the used transfer needle with filter into a sharps disposal container.

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

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

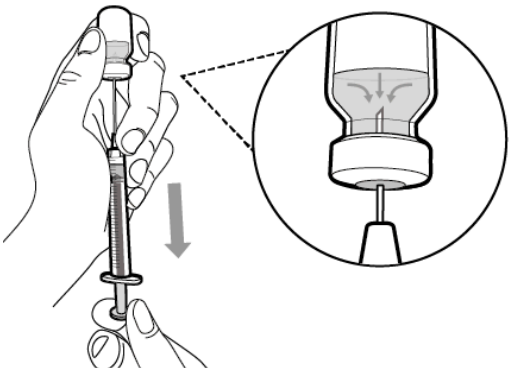
| | |
|---|---|
| **with filter to syringe**<br>  <br> | **filter each time you withdraw medicine from a new vial.**<br>• Push and twist a **new** transfer needle with filter clockwise on to the syringe until it is fully attached.<br>• Slowly pull back the plunger and draw some air into the syringe. |
| **Step D. Uncap transfer needle with filter**<br>  | • Hold the syringe by the barrel with the transfer needle cap pointing up.<br>• 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.<br>• **Do not touch** the needle tip. |
| **Step E. Inject air into vial**<br>  | • 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.

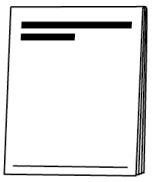
- Check the expiry date on the box, on the vial label and on the supplies listed below. Do not use if the expiry date has passed.

**Do not use the vial if:**

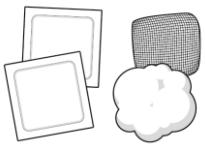
- the medicine is cloudy, hazy or coloured.
- the medicine contains particles.
- the cap covering the stopper is missing.

- 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:**

| | |
|---|---|
| | • Vial containing the medicine |
|  | • Hemlibra instructions for Use |

**NOT INCLUDED IN THE BOX:**

| | |
|---|---|
|  | • **Alcohol wipes**<br>**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.<br>• **Gauze**<br>• **Cotton Ball** |

| | |
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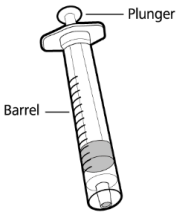
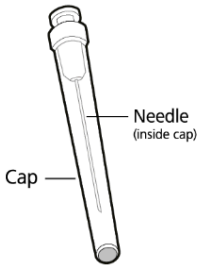
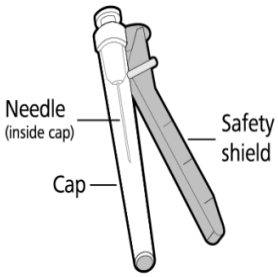
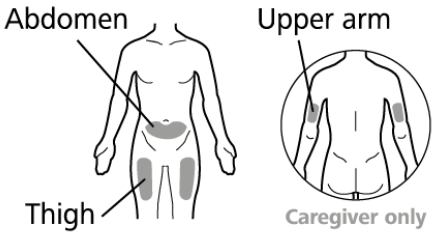
|  <br>  <br>  <br> | • **Syringe**<br>**Note:** For injection amount up to 1 mL use a 1 mL syringe.<br>For injection amount between 1mL and 2 mL use a 2 or 3 mL syringe.<br>• **18G Transfer Needle**<br>**Note:** If you need to use more than 1 vial to inject your prescribed dose, you must use a new transfer needle for each vial.<br>Do not use the transfer needle to inject medicine.<br>• **26G Injection Needle with safety shield**<br>Do not use the injection needle to withdraw medicine from vial.<br><br>Sharps disposal container |

**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:**

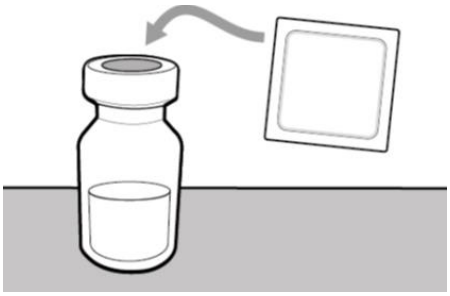
**Important: Always keep the sharps disposal container out of reach of children.**

- 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

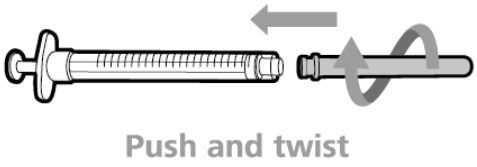
- Take the cap off the vial(s).

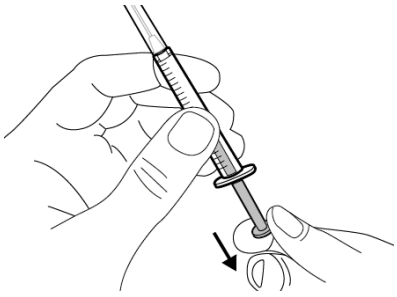


- Clean the top of the vial(s) stopper with an alcohol wipe.
- Dispose of (throw away) the vial cap(s) into the sharps disposal container.

### Step 2. Attach transfer needle to syringe

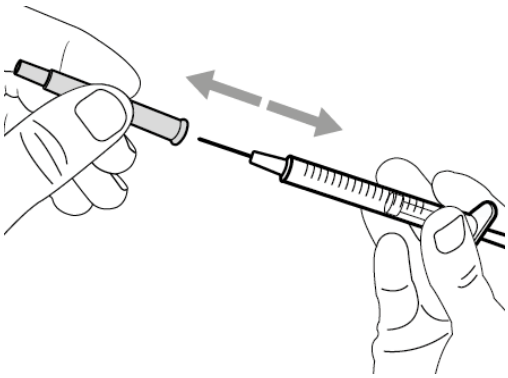
- **Push and twist the transfer needle clockwise** on to the syringe until it is fully attached.
- Slowly pull back on the plunger and draw air into the syringe that is the same amount for your prescribed dose.



### Step 3. Uncap transfer needle

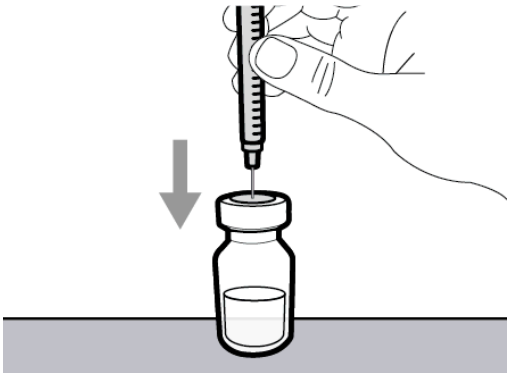
- Hold the syringe by the barrel with the transfer needle pointing up.
- Carefully pull the transfer needle cap straight off and away from your body. **Do**

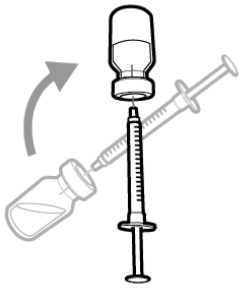


**not throw the cap away. Place the transfer needle cap down on a flat surface.** You will need to recap the transfer needle after transferring the medicine.

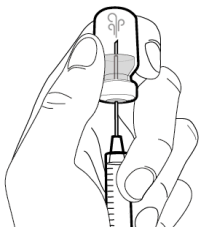
- **Do not touch** the needle tip or place it on a surface after the needle cap has been removed.
- Keep the vial on the flat working surface and insert the transfer needle and syringe straight down into the centre of the vial stopper.

**Step 4. Inject air into vial**



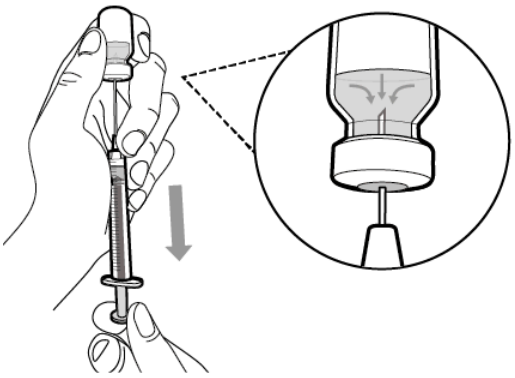


- Keep the needle in the vial and turn the vial upside down.



- 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.

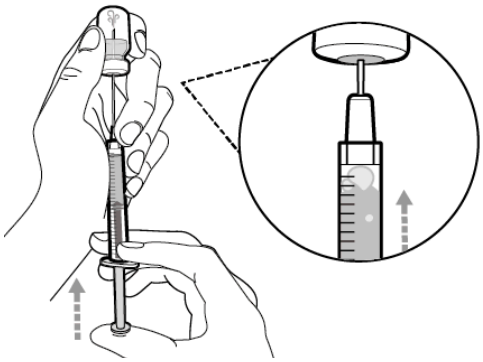
**Step 5. Transfer medicine to syringe**

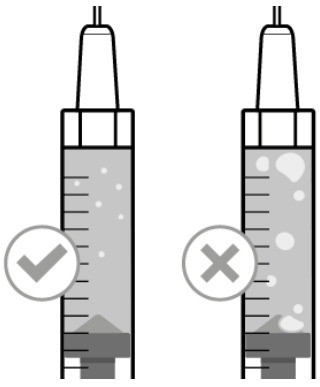


- Slide the tip of the needle down so that it is within the medicine.
- Slowly pull back the plunger to fill the syringe with more than the amount of medicine needed for your prescribed dose.
- Be careful not to pull the plunger out of the syringe.

**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**.

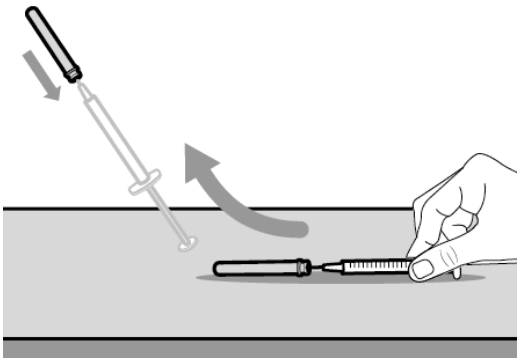
- Be careful not to pull the plunger out of the syringe
- Repeat the steps above until you have removed the larger air bubbles.

**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.

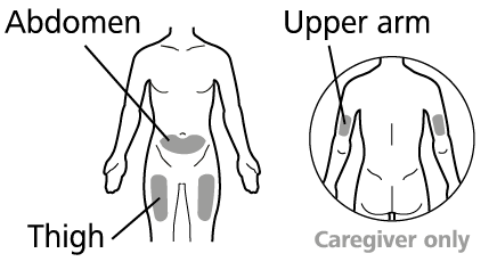
**Do not** use the transfer needle to inject medicine as this may cause harm such as pain and bleeding.

**2. INJECTION**

**Step 7. Recap transfer needle**



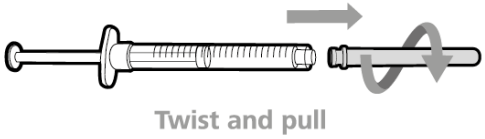
3. Remove the syringe and transfer needle from the vial.
4. **Using one hand, slide** the transfer needle into the cap and **scoop upwards** to cover the needle.
5. Once the needle is covered, push the transfer needle cap towards the syringe to fully attach it with **one hand** to prevent accidentally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




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

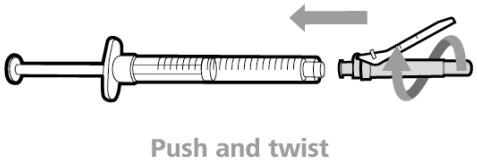
**Step 8. Clean injection site**

**Step 9. Remove transfer needle**



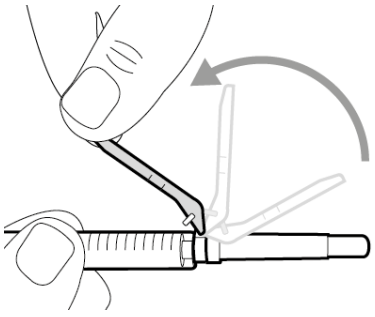

- Remove the transfer needle from the syringe by twisting anticlockwise and gently pulling.
- Dispose of (throw away) the used transfer needle into a sharps disposal container.

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



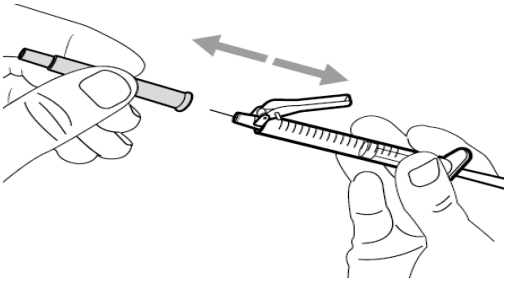

- Push and twist the injection needle clockwise onto the syringe until it is fully attached.

**Step 11. Move safety shield**



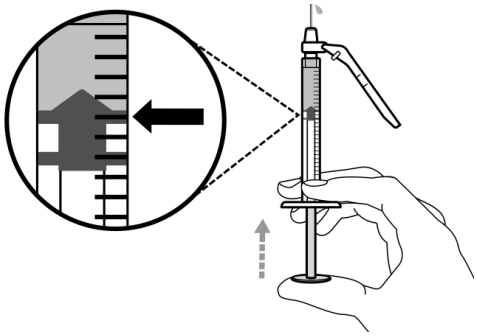
- Move the safety shield away from the needle and **towards** the syringe barrel.

**Step 12. Uncap injection needle**



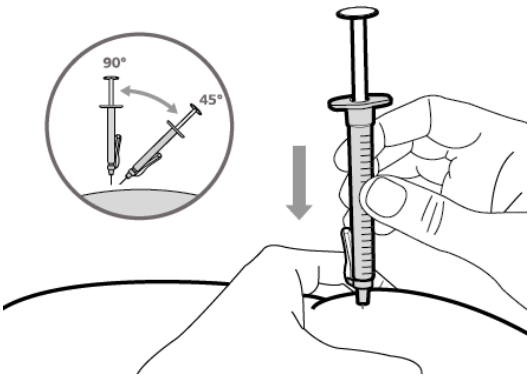
- Carefully pull the injection needle cap straightaway from the syringe.
- Dispose of (throw away) the cap into a sharps disposal container
- **Do not touch** the needle tip or allow it to touch any surface.
- After the injection needle cap has been removed, the medicine in the syringe must be injected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

**Step 13. Adjust plunger to prescribed dose**



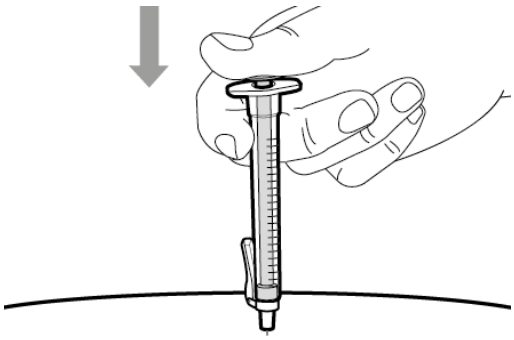
- Hold the syringe with the needle pointing up and slowly push the plunger to your prescribed dose.
- **Check your dose,** ensure the top rim of the plunger is in line with the mark on the syringe for your prescribed dose.

**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.

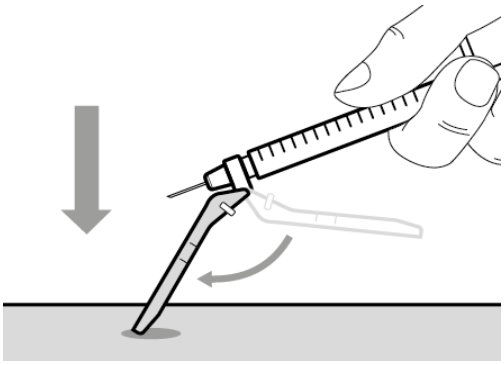
**Step 15. Inject the medicine**



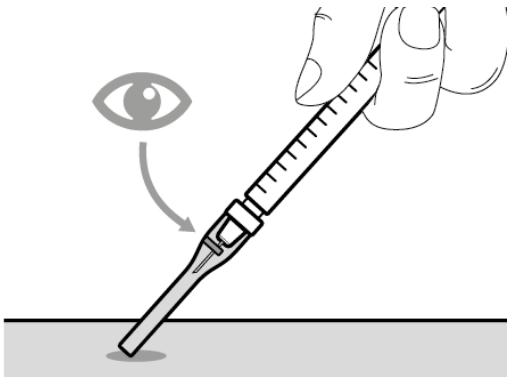
- Slowly inject all of the medicine by gently pushing the plunger all the way down.
- Remove the needle and syringe from the injection site at the same angle as inserted.

**3. DISPOSAL**

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



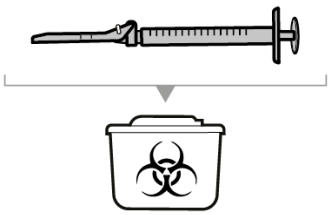
- Move the safety shield forward 90°, away from the syringe barrel.
- Holding the syringe with one hand, **press the safety shield down** against a flat surface with a firm, quick motion until you hear a "click".



- 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



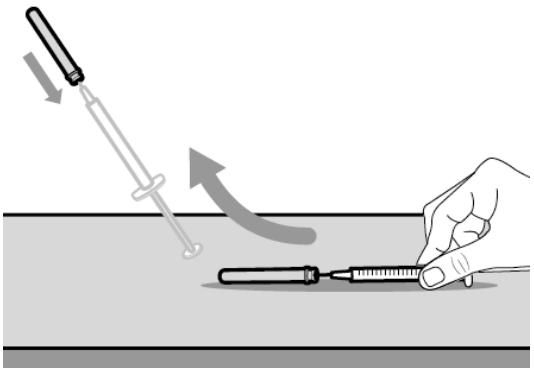
use. For further information refer to the section “Disposing of the medicine and supplies”.

- 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:

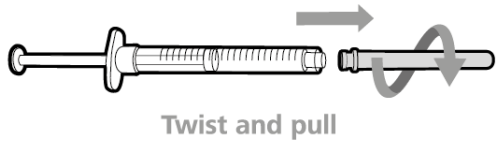
**Step A. Recap transfer needle**



- 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**

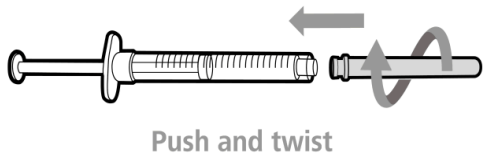
- Remove the transfer needle from the syringe by




twisting anticlockwise and gently pulling.

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

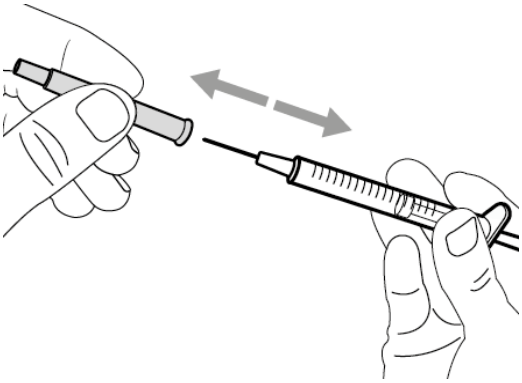
**Step C. Attach a new transfer needle to Syringe**




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

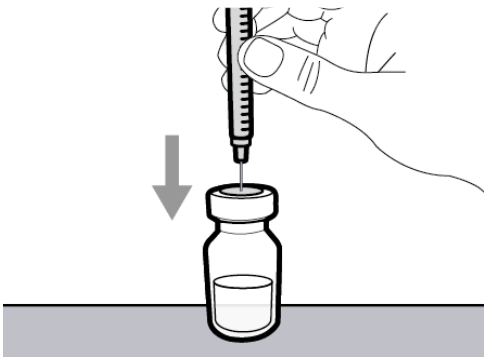
- Push and twist a **new** transfer needle clockwise on to the syringe until it is fully attached.
- Slowly pull back the plunger and draw some air into the syringe.

**Step D. Uncap transfer needle**

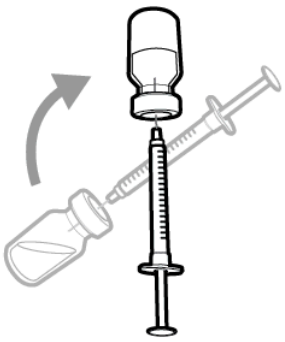


- Hold the syringe by the barrel with the transfer needle cap pointing up.
- Carefully pull the transfer needle cap straight off and away from your body. Do not throw the cap away. You will need to recap the transfer needle after drawing up the medicine.
- Do not touch the needle tip.

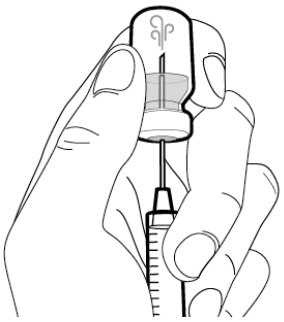
**Step E. Inject air into vial**



- 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.

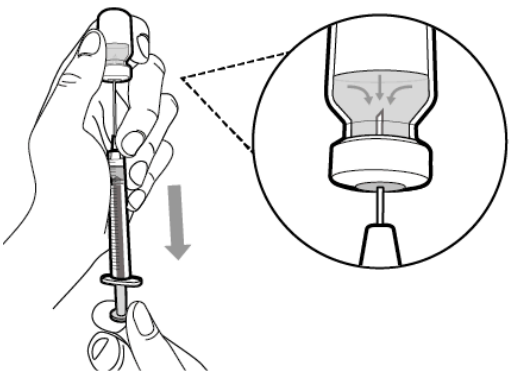


- Keep the transfer needle in the vial and turn the vial upside down.



- 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 that 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.

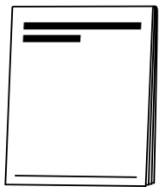
| |
|---|
| Once removed from the refrigerator, the unopened vial can be kept at room temperature for up to 7 days. After storage at room temperature unopened vials may be returned to the refrigerator. The total amount of time outside cold storage and at room temperature should not exceed 7 days. |

- 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.

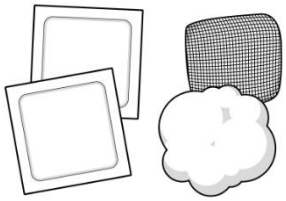
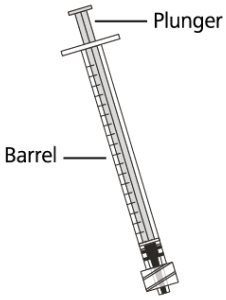
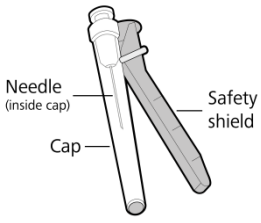
**Inspecting the medicine and your supplies:**

- 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.**

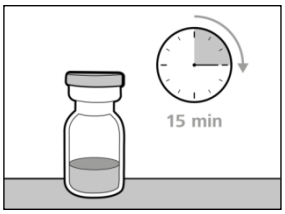
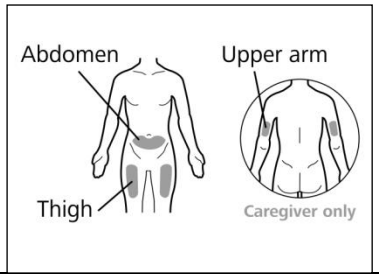
**INCLUDED IN THE BOX:**

| | |
|---|---|
| | • **Vial containing the medicine** |
|  | • **Hemlibra Instructions for Use** |

**NOT INCLUDED IN THE BOX:**

| | |
|---|---|
|  | • **Alcohol wipes**<br>**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.<br>• **Gauze**<br>• **Cotton ball** |
| | • **Vial adaptor** (To be added on top of vial).<br>**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.<br>**Do not insert injection needle into vial adaptor.** |
|  | • Syringe with Low Dead Space (LDS) Plunger<br>Important:<br>○ For injection amount up to 1 mL use a 1 mL LDS syringe.<br>○ For injection amount over 1 mL use 3 mL LDS syringe.<br>**Note**: Do not use 3 mL LDS syringe for doses up to 1 mL. |
|  | • **Injection needle with safety shield** (Used to inject medicine).<br>**Do not** insert the injection needle into vial adaptor or use the injection needle to withdraw medicine from vial. |

| | |
|---|---|
| | • **Sharps disposal container** |

| | |
|---|---|
| **Get ready:**<br>• Before use, allow the vial(s) to reach room temperature for about 15 minutes on a clean flat surface away from direct sunlight.<br>• **Do not** try to warm the vial by any other way.<br>• Wash your hands **well with soap and water.** |  |
| **Selecting and preparing an injection site:**<br>• Clean the chosen injection site area using an alcohol wipe.<br>• 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 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.**

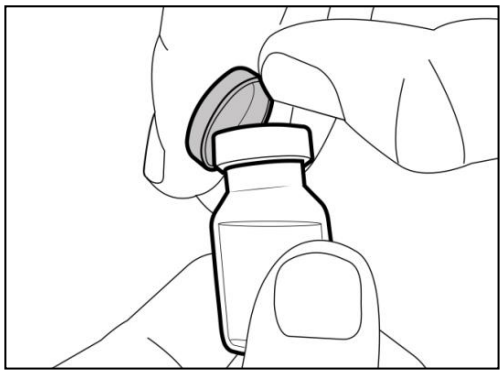
- **Throw away any used caps, vial(s), vial adaptors, needles and syringes in a sharps or puncture-proof container.**
- Put your used vial adaptors, needles and syringes in a sharps disposal container straight away after use. Do not throw away any loose caps, vials, needles and syringes in your household 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.

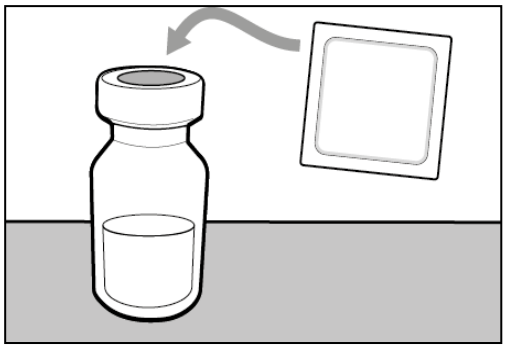
- When your sharps disposal container is almost full, you will need to follow your local guidelines for the right way to throw away of your sharps disposal container.
- Do not throw away any used sharps disposal container in your household waste unless your local guidelines permit this. Do not recycle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

## 1. PREPARATION

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

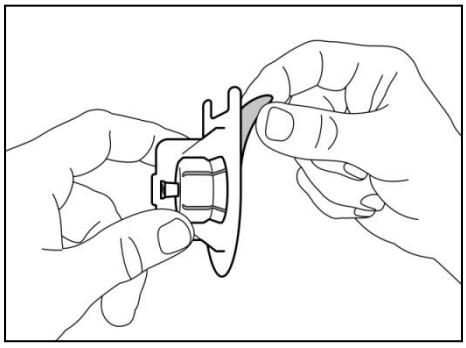


- Take the cap off the vial(s).
- Throw away the vial cap(s) into the sharps disposal container.



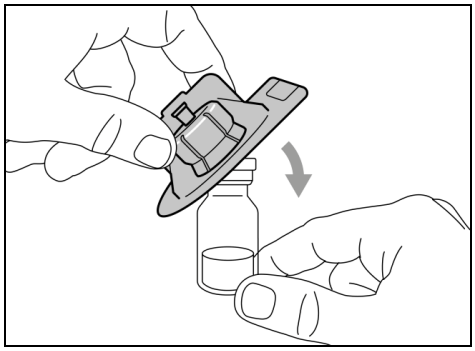
- Clean the top of the vial(s) stopper with an alcohol wipe.

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

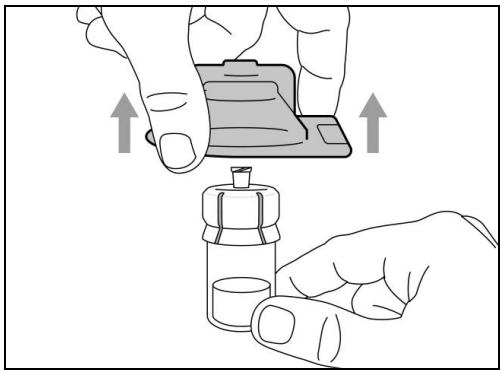


- Peel off back to open the blister pack.

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

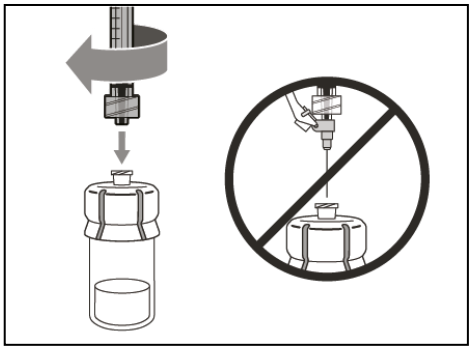


- Firmly press down the plastic blister pack with the vial adaptor onto the new vial at an angle, until you hear a **"click**".



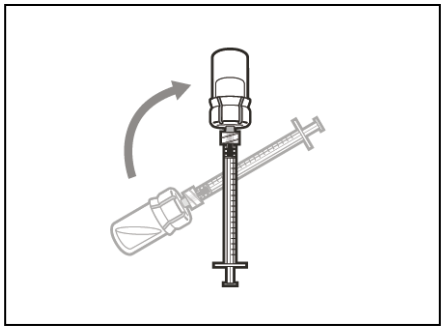
- Remove and throw away the plastic blister pack.
- **Do not** touch the tip of vial adaptor.

**Step 3. Connect syringe to vial adaptor**

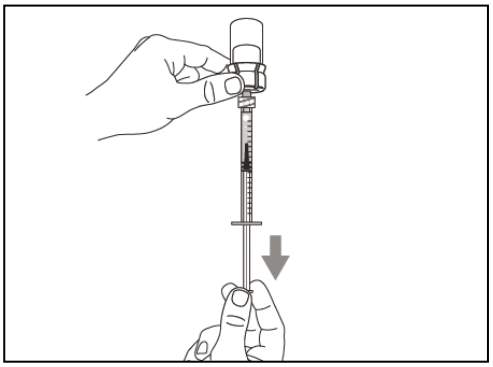


- **Remove syringe cap** (if required).
- **Push and twist the syringe clockwise** on to the vial adaptor until it is fully attached.

**Step 4. Transfer medicine to syringe**



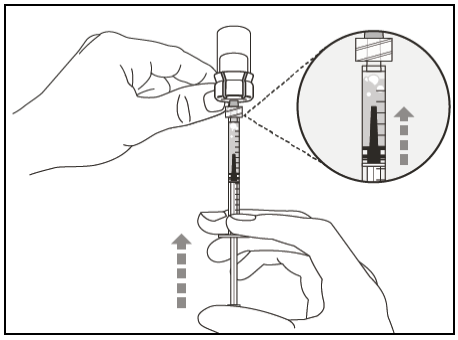
- Keep the vial adaptor attached to the syringe and turn the vial upside down.



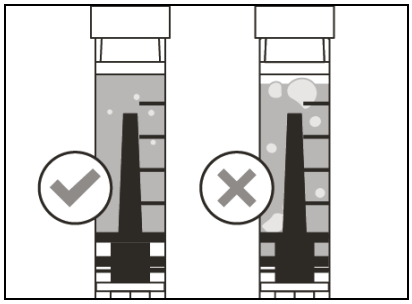
- With the syringe pointing upwards, slowly pull back the plunger to **fill the syringe with** more than the amount **of medicine** needed for your prescribed dose.
- **Hold plunger firmly** to ensure it does not pull back in.
- Be careful not to pull the plunger out of the syringe.

**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.



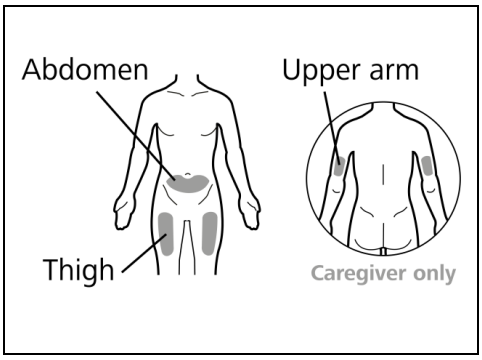
- **Remove the larger air bubbles** by gently **tapping** the syringe barrel with your finger until the air bubbles rise to the top of the syringe. **Slowly push the plunger** to push the large air bubbles out of the syringe.
- If the amount of medicine in the syringe is now at or below your prescribed 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.

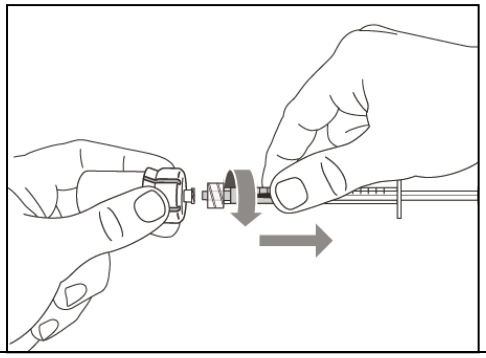
## 2. INJECTION

### Step 6. Clean injection site



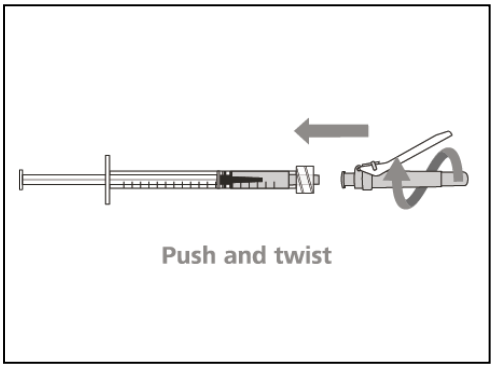

- Select and **clean** your injection site with an alcohol wipe.

### Step 7. Remove syringe from vial adaptor



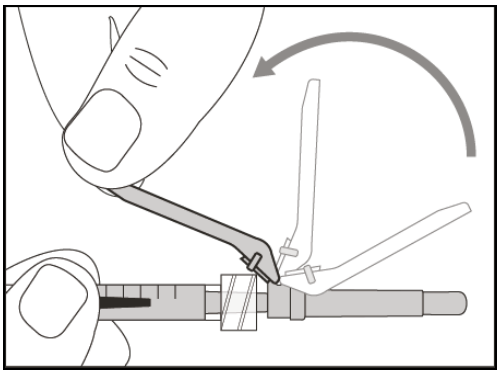
- Remove the syringe from the vial adaptor by twisting anticlockwise and gently pulling.
- Throw away the used vial/vial adaptor into a sharps disposal container.

### Step 8. Attach injection needle to syringe



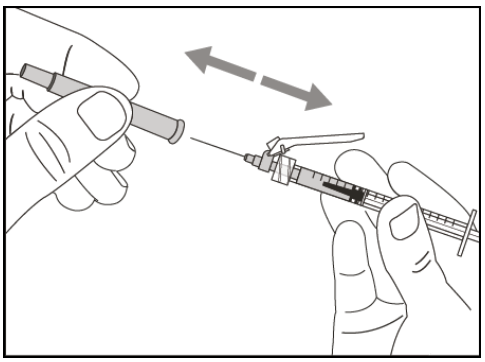

- Push and twist the injection needle clockwise onto the syringe until it is fully attached.
- **Do not** insert the injection needle into vial adaptor or use the injection needle to withdraw medicine from vial.

**Step 9. Move safety shield**



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

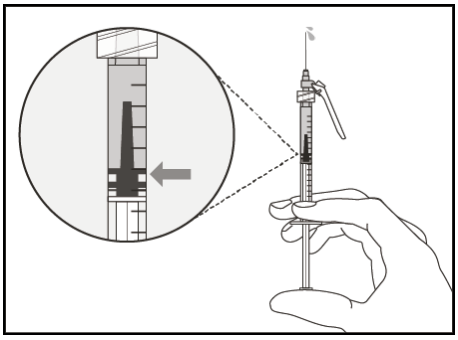
**Step 10. Uncap injection needle**



- **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.

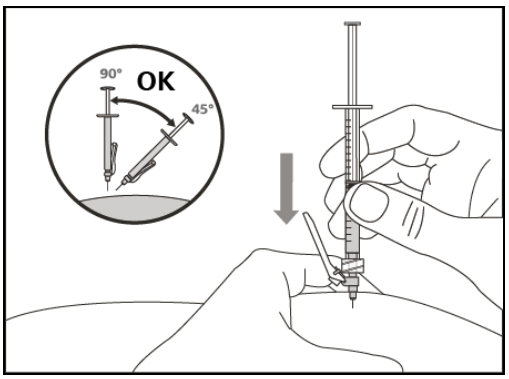
**Step 11. Adjust plunger to prescribed dose**

- 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



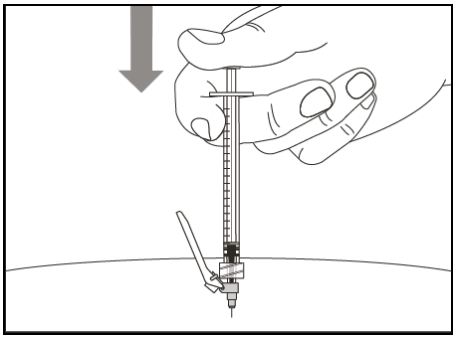
syringe for your prescribed dose.

**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.

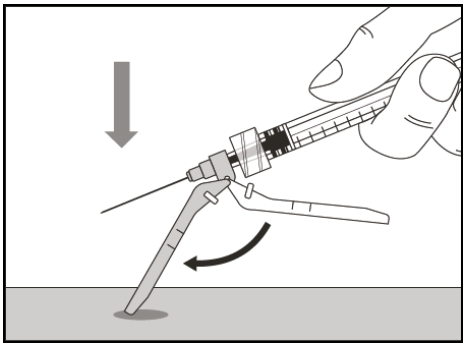
**Step 13. Inject the medicine**



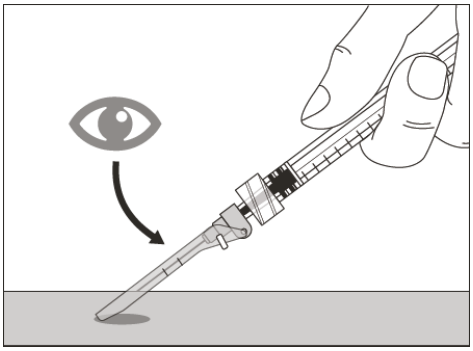
- Slowly inject all of the medicine by gently pushing the plunger all the way down.
- Remove the needle and syringe from the injection site at the same angle as inserted.

## 3. DISPOSAL

**Step 14. Cover needle with safety shield**

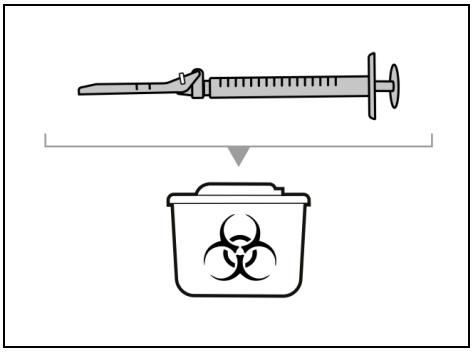


- Move the safety shield forward 90°, away from the syringe barrel.
- **Holding the syringe with one hand**, **press the safety shield down** against a flat surface with a firm, quick motion until you hear a “click”.



- 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**

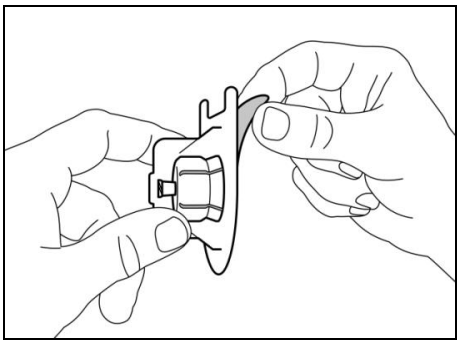


- Put your used needles and syringes in a sharps disposal container right away after use. For further information refer to the section “Disposing of the medicine and supplies”.
- **Do not** try to remove the used injection needle from the used syringe.
- **Do not recap** the injection needle with the 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.

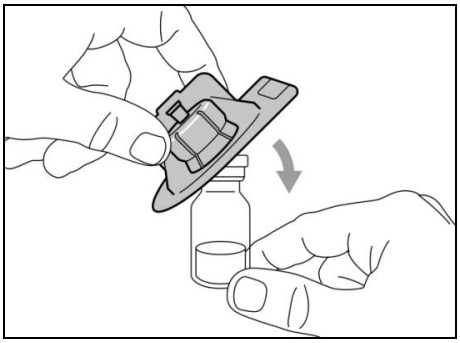
**Combining Vials**

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:

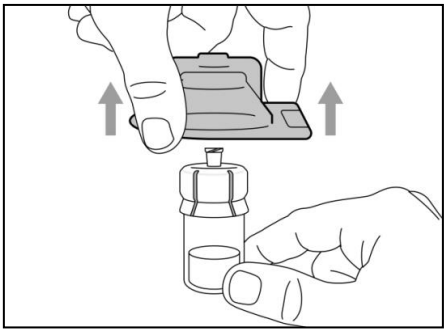
**Step A. Insert new vial adaptor into new vial**



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

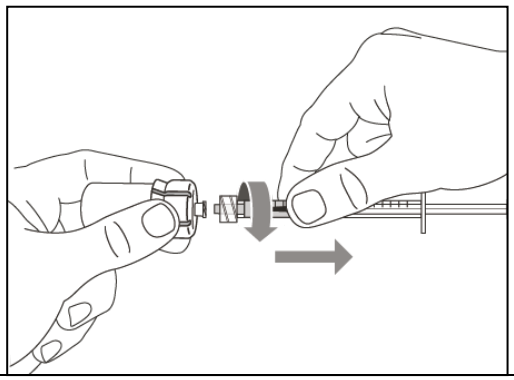


- Firmly press down the plastic blister pack with the vial adaptor onto the new vial at an angle, until you hear a **'click'**.



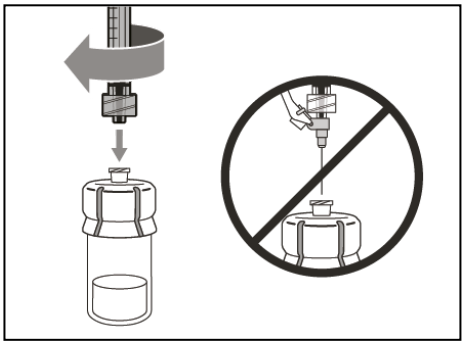
- Remove and throw away the plastic blister pack.
- **Do not** touch the tip of vial adaptor.

**Step B. Remove used vial adaptor**



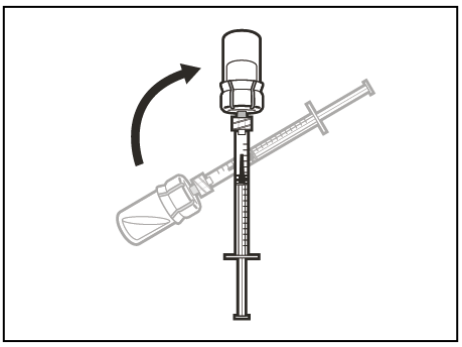
- Remove the used vial adaptor from the syringe by twisting anticlockwise and gently pulling.
- Throw away the used vial/vial adaptor into a sharps disposal container.

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

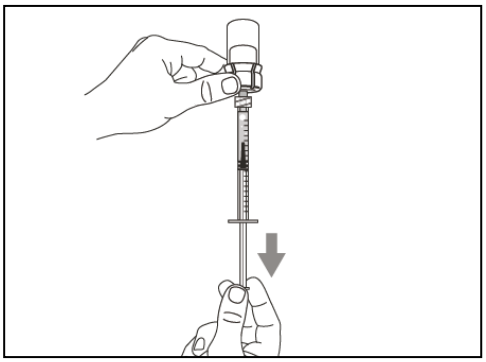


- **Push and twist the syringe clockwise** on to the vial adaptor until it is fully attached.

**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 5 "Remove air bubbles". Continue with the remaining steps.**