



Transfer Needle with Filter Option

(For transfer of Hemlibra from vial to syringe)



Instructions for Use
Hemlibra (emicizumab)
Injection
Single-Dose Vial(s)

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 Vial Adapter with filter to withdraw Hemlibra from the vial. The instructions are for use with the Transfer Needle with filter only.

- **Do not** inject yourself or someone else unless you have been shown how to by your healthcare provider.
- 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) 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. Speak to your pharmacist to find out the best way to dispose of any unused medicine.
- **Only use the syringes, transfer needles, and injection needles indicated for use with Hemlibra.**
- **Use the syringes, transfer needles and injection needles only once. Throw away used caps, vials, syringes and needles in a sharps disposal container. Speak to your pharmacist to find out the best way to dispose of the sharps disposal container.**
- 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. Do not inject the medicine intravenously.

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 (2°C to 8°C).
- **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 (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.
- 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.

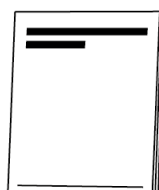
Inspecting the medicine and your supplies

- 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:

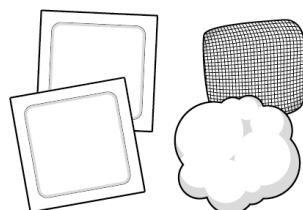


- **Vial containing the medicine**



- **Instructions for Use**

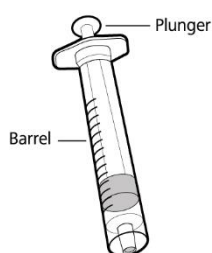
NOT INCLUDED IN THE BOX:



- **Alcohol wipes**

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

- **Gauze**
- **Cotton ball**

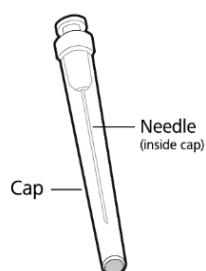


- **Syringe**

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

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

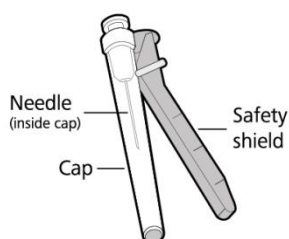
Note: Do not use 2 mL or 3 mL syringe for doses up to 1 mL.



- **18G transfer needle with 5 micron filter**

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

Do not use the transfer needle to inject the medicine.



- **26G injection needle with safety shield**

Do not use the injection needle to withdraw medicine from vial.



- **Sharps disposal container**

Get ready

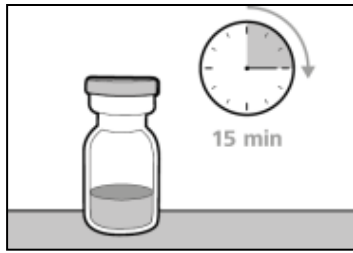


Figure A

- Before use, allow the vial(s) to reach 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

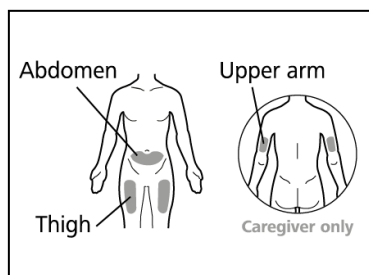


Figure B

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

For your injection, you can use your:

- Thigh (front and middle).
- Stomach area (abdomen), except for 5 cm around the navel (belly button).
- Outer area of the upper arm (only if a caregiver is giving the injection).
- You should use a different injection site 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 applied with gentle pressure on the site. If bleeding does not stop, please contact your healthcare provider.

Disposing of the medicines and supplies

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

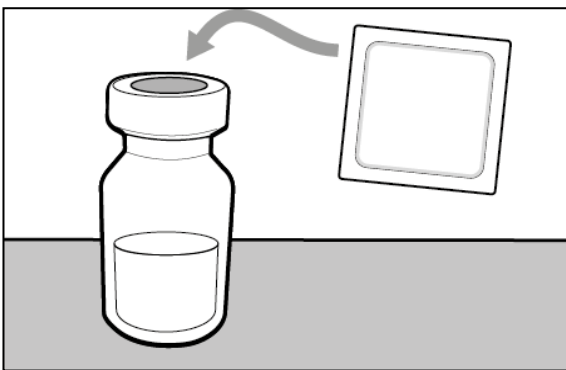
- **Throw away any used caps, vial(s), needles and syringes in a sharps disposal container.** Put your used needles and syringes in a sharps disposal container straight away after use. **Do not** throw away any loose caps, vials, needles and syringes in your household waste.
- When your sharps disposal container is almost full, you will need to follow your local guidelines or speak to your pharmacist 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

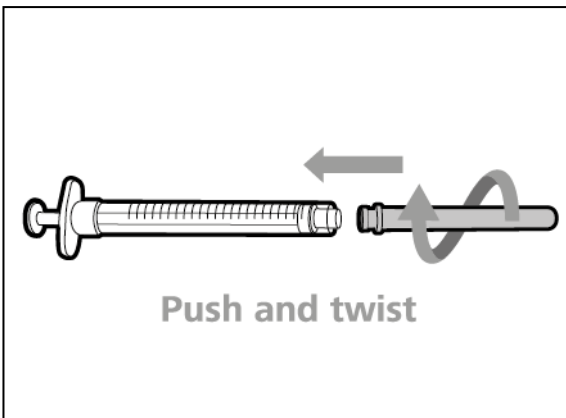


- Take the cap off the vial(s).
- Throw away the vial cap(s) into the sharps disposal container.

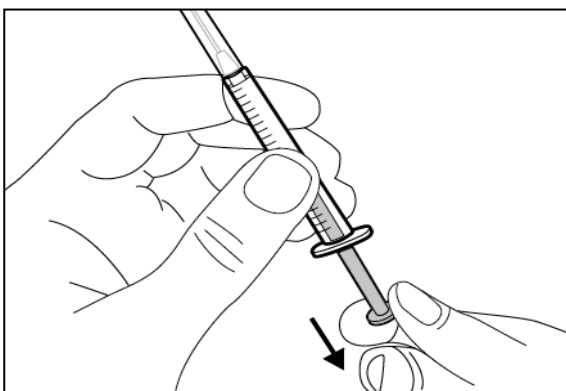


- Clean the top of the vial(s) stopper with an alcohol wipe.

Step 2. Attach transfer needle to syringe

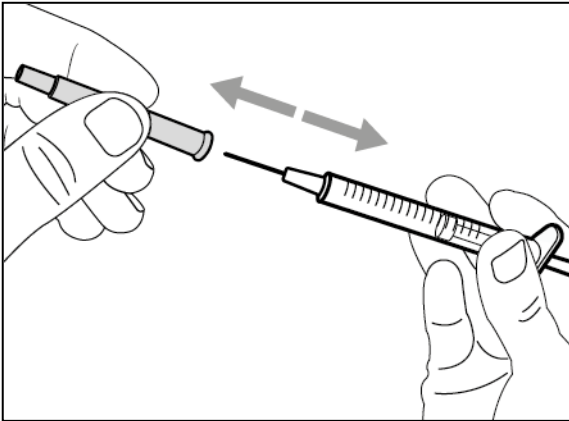


- **Push and twist the transfer needle clockwise** onto the syringe until it is fully attached.



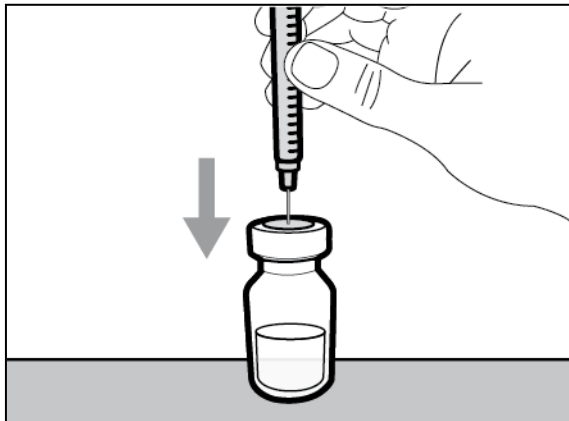
- Slowly pull back on the plunger and draw air into the syringe that is the same amount as your prescribed dose.

Step 3. Uncap transfer needle

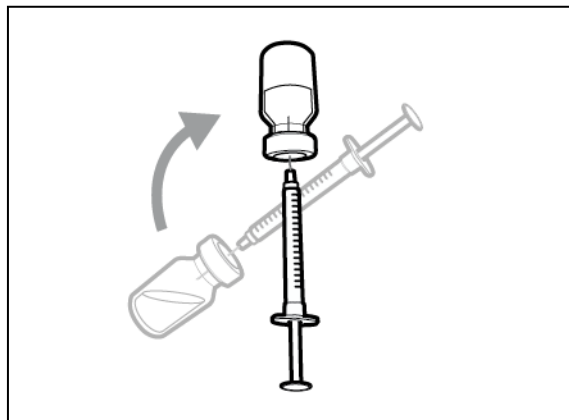


- Hold the syringe by the barrel with the transfer needle pointing up.
- Carefully pull the transfer needle cap straight off and away from your body. **Do not throw the cap away. Place the transfer needle cap down on a clean flat surface.** You will need to recap the transfer needle after transferring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

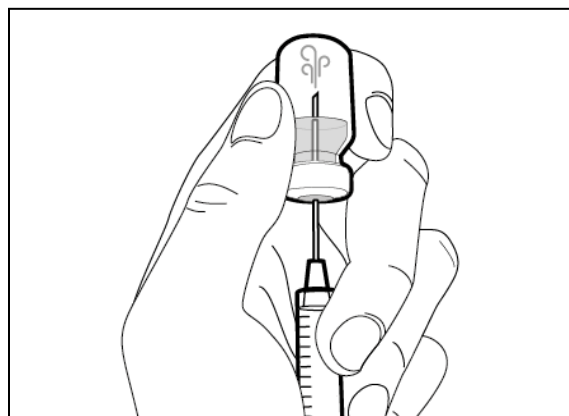
Step 4. Inject air into vial



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

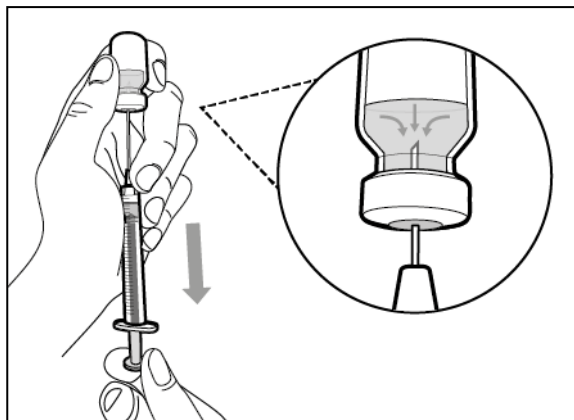


- Keep the needle in the vial and turn the vial upside down.



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

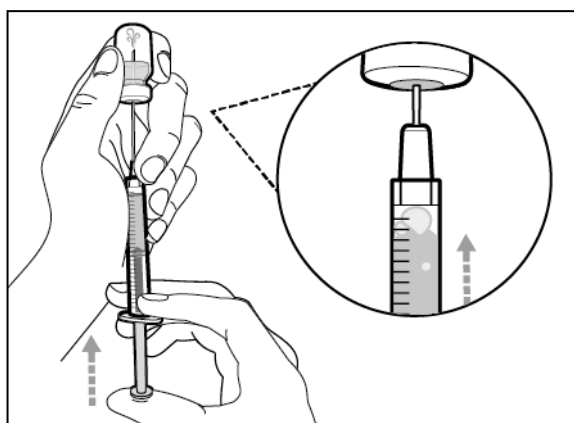
Step 5. Transfer medicine to syringe



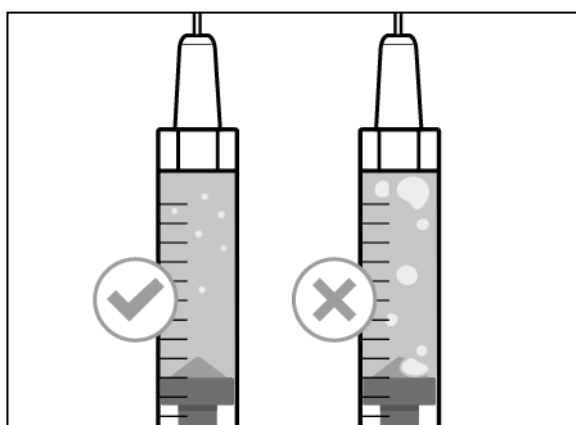
- Slide the tip of the needle down so that it is **within the medicine**.
- With the syringe pointing upwards, slowly pull back the plunger to prevent air bubbles/foam. Fill the syringe with more than the amount of medicine needed for your prescribed dose.
- Be careful not to pull the plunger out of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

Important: If your prescribed dose is more than the amount of Hemlibra 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 bubbles 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.



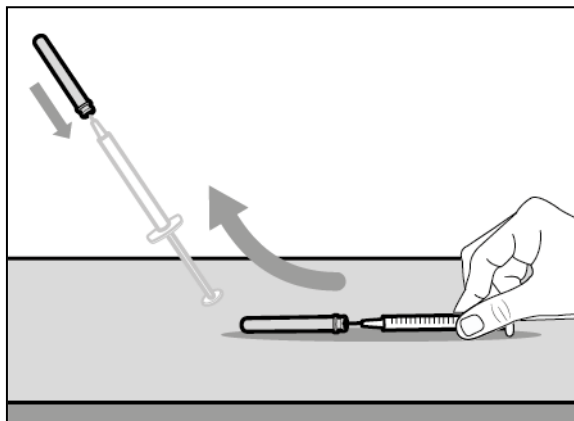
- If the amount of medicine in the syringe is now at or below your prescribed dose, move the tip of the needle to **within the medicine** and slowly pull back the plunger until you have **more** than the amount of medicine needed for your **prescribed dose**.
- Be careful not to pull the plunger out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

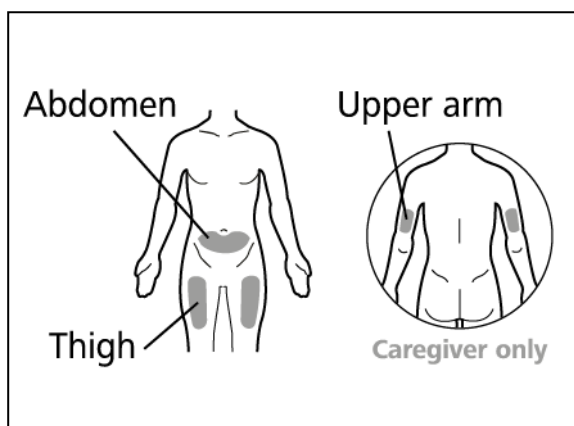
2. INJECTION

Step 7. Recap transfer needle



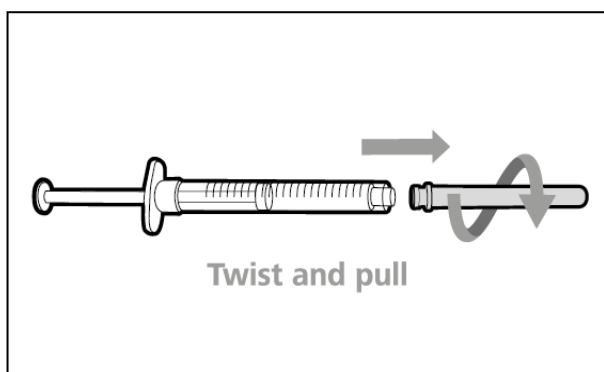
- Remove the syringe and transfer needle from the vial.
- **Using one hand, slide** the transfer needle into the cap and **scoop upwards** to cover the needle.
- Once the needle is covered, push the transfer needle cap towards the syringe to fully attach it with **one hand** to prevent accidentally injuring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

Step 8. Clean injection site



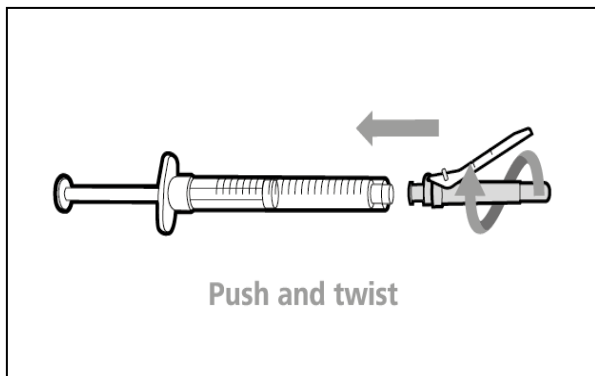
- Select and **clean** your injection site with an alcohol wipe.

Step 9. Remove the used transfer needle from the syringe



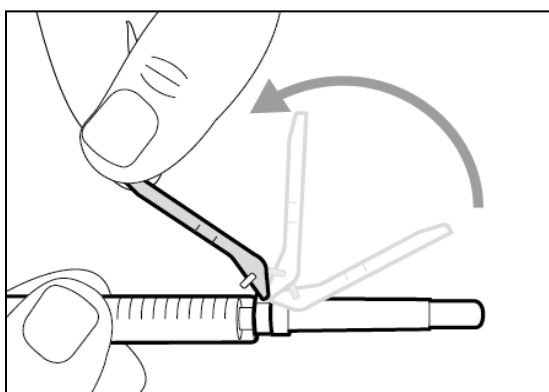
- Remove the used transfer needle from the syringe by twisting anti-clockwise and pulling gently.
- Throw away the used transfer needle into a sharps disposal container.

Step 10. Attach injection needle to syringe



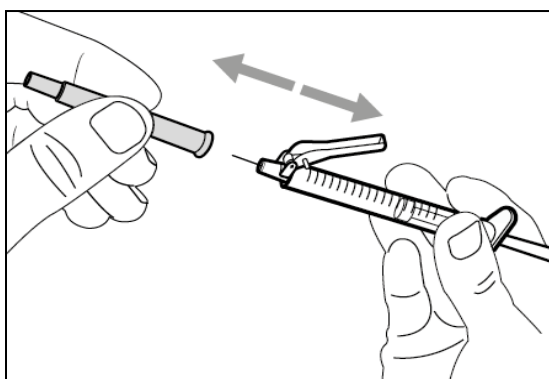
- Push and twist the injection needle clockwise onto the syringe until it is fully attached.

Step 11. Move safety shield



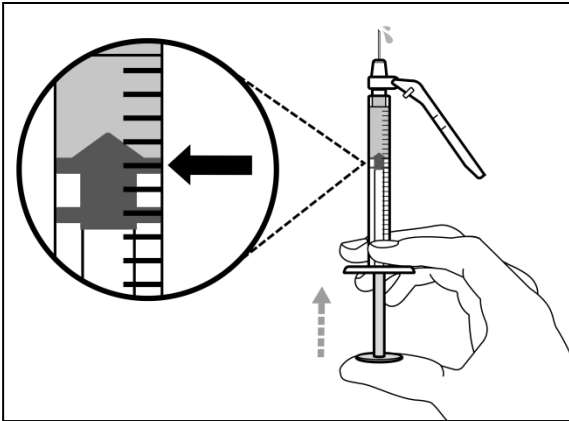
- Move the safety shield away from the needle and **towards** the syringe barrel.

Step 12. Uncap injection needle



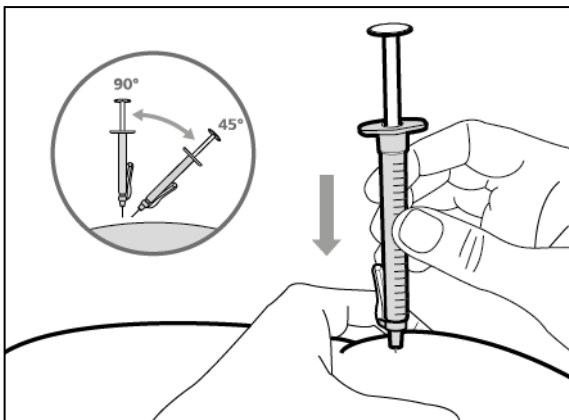
- **Carefully** pull the injection needle cap **away** from the syringe.
- Throw away the cap into a sharps disposal container.
- **Do not touch** the needle tip or allow it to touch any surface.
- After the injection needle cap has been removed, the medicine in the syringe must be injected within 5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

Step 13. Adjust plunger to prescribed dose



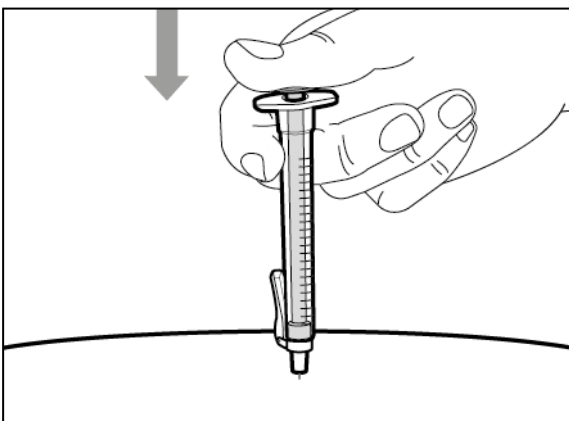
- Hold the syringe with the needle pointing up and slowly push the plunger to your prescribed dose.
- **Check your dose.** Ensure the top rim of the plunger is in line with the mark on the syringe for your prescribed dose.

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.

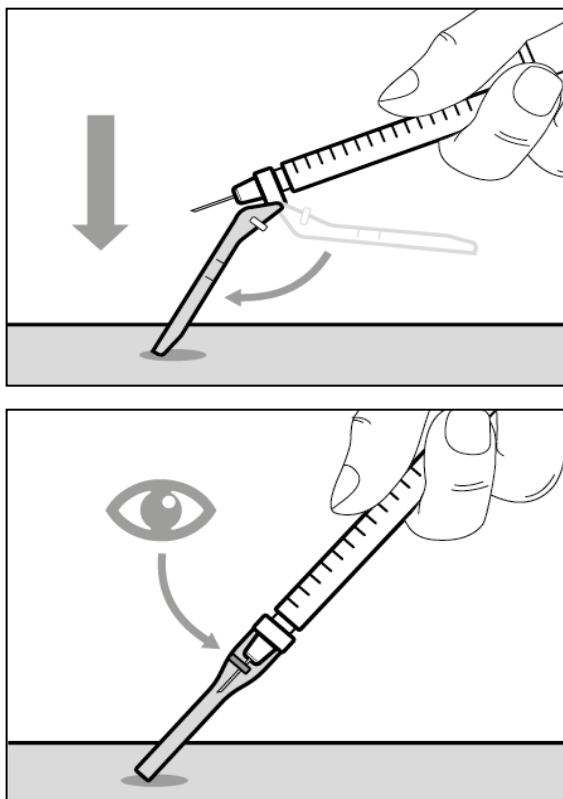
Step 15. Inject the medicine



- 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.

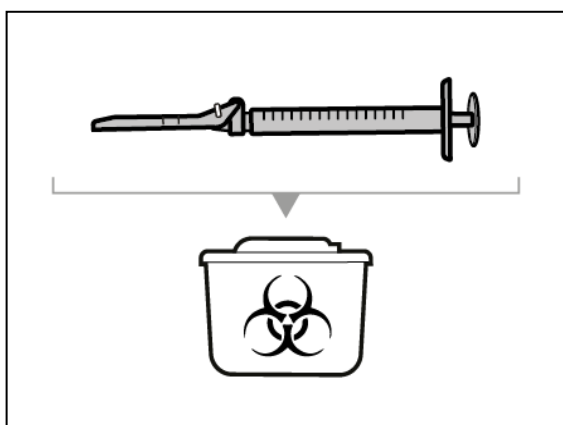
3. DISPOSAL

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 the injection needle

Step 17. Throw away the syringe and needle

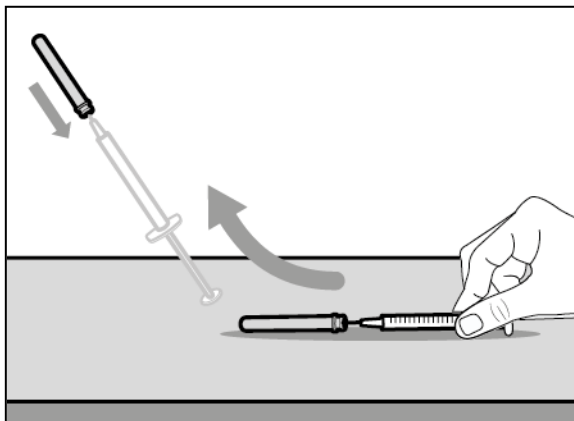


- Put your used needles, syringes, caps and vials in a sharps disposal container right away after use. For further information refer to the section “Disposing of sharps”.
- **Do not** try to remove the used injection needle from the used syringe.
- **Do not recap** the injection needle with the cap.
- **Important:** Always keep the sharps disposal container out of reach of children.

Combining Vials

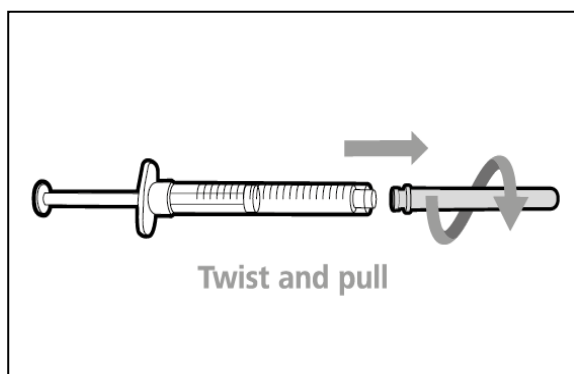
If you need to use more than 1 vial to get to your total prescribed dose, follow these steps after you have drawn up the medicine from the first vial.

Step A. Recap transfer needle



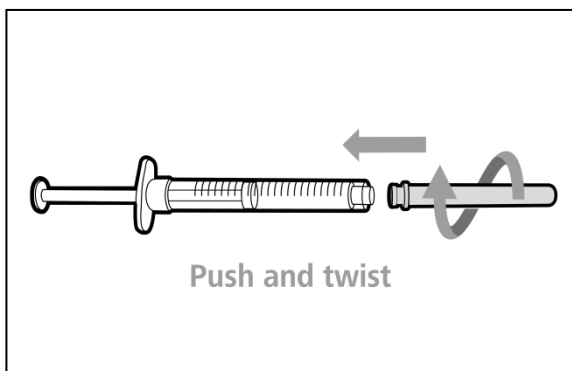
- Remove the syringe and transfer needle from the first vial.
- **Using one hand**, slide the transfer needle into the cap and **scoop upwards** to cover the needle.
- Once the needle is covered, push the transfer needle cap toward the syringe to fully attach it with **one hand** to prevent accidentally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

Step B. Remove the used transfer needle from the syringe



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

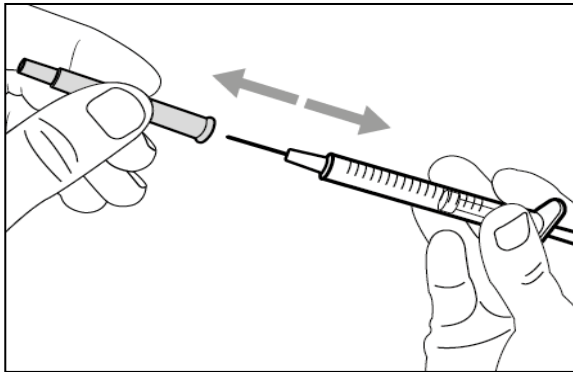
Step C. Attach a new transfer needle to syringe



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

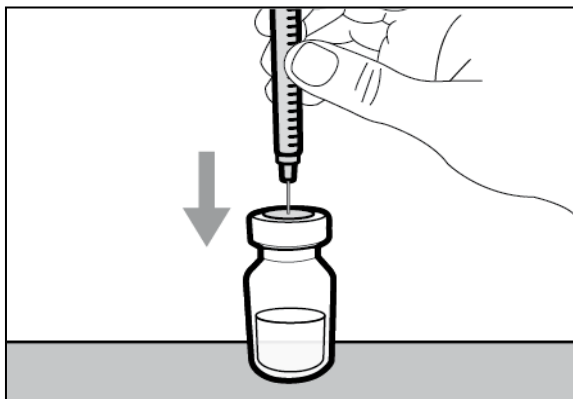
- Push and twist a **new** transfer needle clockwise on to the syringe until it is fully attached.
- Slowly pull back the plunger and draw some air into the syringe.

Step D. Uncap transfer needle

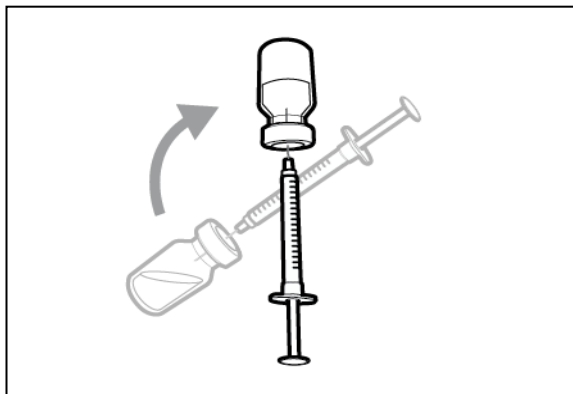


- Hold the syringe by the barrel with the transfer needle cap pointing up.
- Carefully pull the transfer needle cap straight off and away from your body. **Do not throw the cap away.** You will need to recap the transfer needle after drawing up the medicine.
- **Do not touch** the needle tip.

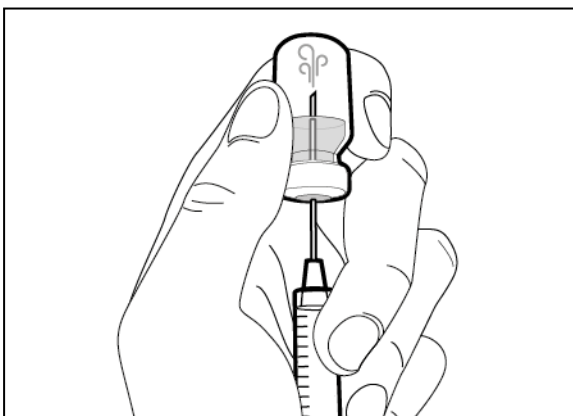
Step E. Inject air into vial



- 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.

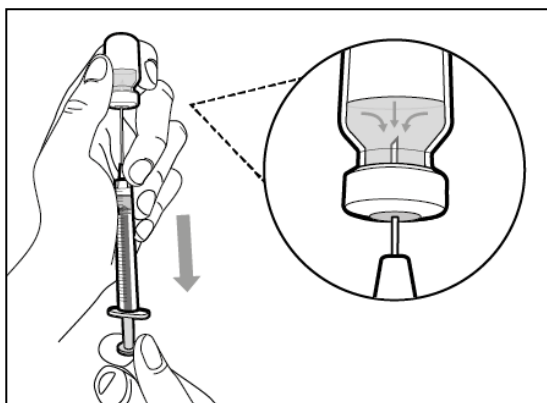


- Keep the transfer needle in the vial and turn the vial upside down.



- 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 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**.
- With the syringe pointing upwards, **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.

Note: Ensure you have enough medicine in the syringe to complete your dose before moving on to the next step. If you cannot remove all 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 the amount of medicine needed for your prescribed dose. Once completed, keep the transfer needle inserted in the vial and return to Step 6 “Remove air bubbles”. Continue with the remaining steps.

Roche Products Pty Limited
ABN 70 000 132 865
Level 8, 30-34 Hickson Road
Sydney NSW 2000
AUSTRALIA

Medical Information: www.medinfo.roche.com/australia or 1800 233 950.