

Package leaflet: Information for the user

Hemlibra 150 mg/mL solution for injection emicizumab

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Hemlibra is and what it is used for
2. What you need to know before you use 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 contains the active substance “emicizumab”. This belongs to a group of medicines called “monoclonal antibodies”. Monoclonal antibodies are a type of protein that recognise and bind to a target in the body.

What Hemlibra is used for

Hemlibra is a medicine 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.

The medicine 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 activated 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

Do not use Hemlibra:

- if you are allergic to emicizumab or any of the other ingredients of this medicine (listed in section 6). If you are not sure, talk to your doctor, pharmacist or nurse before using Hemlibra.

Warnings and precautions

Before you start using Hemlibra, it is very important to talk to your doctor about using “bypassing agents” (medicines that help blood clot but which work in a different way from factor VIII). **This is because treatment with bypassing agents may need to change while receiving Hemlibra.** Examples of bypassing agents include activated prothrombin complex concentrate (aPCC) and recombinant FVIIa (rFVIIa). Serious and potentially life-threatening side effects can occur when aPCC is used in patients who are also receiving Hemlibra:

Potentially serious side effects of using aPCC while receiving Hemlibra

- **Destruction of red blood cells (thrombotic microangiopathy)**
 - This is a serious and potentially life-threatening condition.
 - When people have this condition, the lining of the blood vessels can be damaged and blood clots may develop in small blood vessels. In some cases, this can cause damage to the kidneys and other organs.
 - Be cautious if you are at high risk for this condition (have had this condition in the past, or a member of your family have suffered from it), or if you are taking medicines that can increase the risk of developing this condition, such as ciclosporin, quinine or tacrolimus.
 - It is important to know the symptoms of thrombotic microangiopathy, in case you develop the condition (see section 4, “Possible side effects” for a list of symptoms).

Stop using Hemlibra and aPCC, and talk to a doctor immediately if you or your caregiver notices any symptoms of thrombotic microangiopathy.

- **Blood clots (thromboembolism)**
 - In rare cases, a blood clot can form inside blood vessels and block them, which may be life-threatening.
 - It is important to know the symptoms of such internal blood clots, in case they develop (see section 4, “Possible side effects” for a list of symptoms).

Stop using Hemlibra and aPCC, and talk to a doctor immediately if you or your caregiver notices any symptoms of blood clots in blood vessels.

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

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

- Using a bypassing agent while receiving Hemlibra
 - **Before you start using Hemlibra, talk to your doctor and carefully follow their instructions on 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 before starting Hemlibra.
 - Use aPCC **only if** no other treatment can be used. If aPCC is required, talk to your doctor in case you feel you need a total of more than 50 units/kg of aPCC. For more information on using aPCC while receiving Hemlibra, see in section 2: “Potentially serious side effects of using aPCC while receiving Hemlibra”.
 - Despite limited experience with concomitant administration of anti-fibrinolytics with aPCC or rFVIIa in patients treated with Hemlibra, you should know that there may be a possibility of thrombotic events using anti-fibrinolytics administered intravenously in combination with aPCC or rFVIIa.

Laboratory tests

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

Pregnancy and breast-feeding

- You should use an effective method of birth control (contraception) during treatment with Hemlibra and for 6 months after your last injection of Hemlibra.
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. Your doctor will consider the benefit of you taking Hemlibra against the risk to your baby.

Driving and using machines

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

3. How to use Hemlibra

Hemlibra is provided in single-use vials as ready to use solution which does not need to be diluted. A doctor qualified to care for patients with haemophilia will start you on treatment with Hemlibra. Always use this medicine exactly as your doctor has told you. Check with your healthcare provider if you are not sure.

Keeping a record

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

How much Hemlibra to use

The dose of Hemlibra depends on your weight and your doctor will calculate the amount (in mg) and corresponding amount of Hemlibra solution (in mL) to be injected:

- Loading dose regimen: Weeks 1 to 4: The dose is 3 milligrams for every 1 kilogram you weigh, injected once a week.

- Maintenance dose regimen: Week 5 and onwards: The dose is either 1.5 milligrams for every 1 kilogram you weigh, injected once a week, 3 milligrams for every 1 kilogram you weigh, injected every 2 weeks, or 6 milligrams for every 1 kilogram you weigh, injected every 4 weeks.

The decision, to use either the 1.5 mg/kg once weekly, 3 mg/kg every two weeks, or 6 mg/kg every four weeks maintenance dose, should be made in consultation with your doctor and, where applicable, with your caregiver.

Different Hemlibra concentrations (30 mg/mL and 150 mg/mL) **should not** be combined in a single injection when making up the total volume to be injected.

The amount of Hemlibra solution given in each injection must not be more than 2 mL

How Hemlibra is given

If you inject Hemlibra yourself or if your caregiver injects it, you or your caregiver must carefully read and follow the instructions in section 7, “Instructions for use”.

- Hemlibra is given by injection under the skin (subcutaneously).
- Your doctor or nurse will show you how to inject Hemlibra.
- Once you have been trained, you should be able to inject this medicine at home, by yourself or with the help of a caregiver.
- 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 cause discomfort.
- Prepare and give the injection in clean and germ-free conditions using aseptic technique. Your doctor or nurse will give more information about this.

Where to inject Hemlibra

- Your doctor will show you which areas of the body are suitable for injecting 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. Use only recommended places for injection.
- For each injection, use a different area of the body to the one you used last time.
- Do not give injections where the skin is red, bruised, tender, hard, or areas where there are moles or scars.
- When using Hemlibra, any other medicine injected under the skin should be given in a different area.

Using syringes and needles

- A syringe, a transfer needle (or vial adapter), and an injection needle are needed to draw up the Hemlibra solution from the vial into the syringe and to inject it under the skin.
- Syringes, transfer needles, vial adapters and injection needles are not provided in this pack. For more information, see in section 6 “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 adapter, a low dead space plunger syringe must be used.

Use in children and adolescents

Hemlibra can be used in adolescents and children of all ages.

- A child can self-inject the medicine provided the child's healthcare provider and the parent or caregiver agree. Self-injection for children below the age of 7 years is not recommended.

If you use more Hemlibra than you should

If you use 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 use Hemlibra

- If you forget your scheduled injection, inject the forgotten dose as soon as possible before the day of the next scheduled dose. Then, continue to inject the medicine as scheduled. Do not inject two doses on the same day to make up for a forgotten dose.
- If you are not sure what to do, ask your doctor, pharmacist or nurse.

If you stop using 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 this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects of using aPCC while receiving Hemlibra

Stop using Hemlibra and aPCC 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 belly (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 problems with your vision – 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.

Other side effects when using Hemlibra

Very common: may affect more than 1 in 10 people

- a reaction in the area where the injection is given (redness, itching, pain)
- headache
- joint pain

Common: may affect up to 1 in 10 people

- fever
- muscle aches
- diarrhoea

Uncommon: may affect up to 1 in 100 people

- destruction of red blood cells (thrombotic microangiopathy)
- 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)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

Malta

ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

United Kingdom

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Hemlibra

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the vial label after “EXP”. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C). Do not freeze.

Store in the original pack in order to protect from light.

Once removed from the refrigerator, unopened vials may be kept at room temperature (below 30°C) for up to 7 days. After storage at room temperature, unopened vials may be returned back to the refrigerator. The total time the medicine is stored at room temperature should not be more than 7 days.

Discard vials that have been kept at room temperature for more than 7 days or exposed to temperatures above 30°C.

Once transferred from the vial to the syringe, use Hemlibra straight away. Do not refrigerate the solution in the syringe.

Before using the medicine, check the solution for particles or discoloration. The solution should be colourless to slightly yellow. Do not use this medicine if it is cloudy, discoloured, or contains visible particles.

Throw away any unused solution appropriately. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Hemlibra contains

- The active substance is emicizumab. Each vial of Hemlibra contains 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-histidine, L-aspartic acid, poloxamer 188 and water for injections.

What Hemlibra looks like and contents of the pack

Hemlibra is a solution for injection. It is a colourless to slightly yellow liquid.

Each pack of Hemlibra contains 1 glass vial.

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

A syringe, a transfer needle (or vial adapter), and an injection needle are needed to withdraw the Hemlibra solution from the vial to a syringe and inject it under the skin (see section 7, “Instructions for use”).

Syringes

- **1 mL syringe:** Transparent polypropylene or polycarbonate syringe with Luer-lock tip, graduation 0.01 mL **or**
- **2 to 3 mL syringe:** Transparent polypropylene or polycarbonate syringe with Luer-lock tip, graduation 0.1 mL.

Needles

- **Transfer needle:** Stainless steel with Luer-lock connection, gauge 18 G, length 35mm (1½”), preferably semi-blunted tip, **and**
- **Injection needle:** Stainless steel with Luer-lock connection, gauge 26 G (acceptable range: 25-27 gauge), length preferably 9 mm (3/8”) or maximally 13mm (½”), preferably including needle safety feature.

Vial adapters

- Polycarbonate with Luer-lock connection, sterile, fitting 15 mm vial neck outer diameter, single-use, latex-free and non-pyrogenic.

Marketing Authorisation Holder

Roche Registration GmbH
Emil-Barell-Strasse 1
79639 Grenzach-Wyhlen
Germany

Manufacturers

Roche Pharma AG
Emil-Barell-Strasse 1
D-79639 Grenzach-Wyhlen
Germany

Roche Austria GmbH
Engelhorngasse 3
A-1211 Wien
Austria

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Ireland

Roche Products (Ireland) Ltd.
Tel: +353 (0) 1 469 0700

Malta

(See Ireland)

United Kingdom

Roche Products Ltd.
Tel: +44 (0) 1707 366000

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>

Instructions for use

Transfer Needle

Option

(For transfer of HEMLIBRA from vial to syringe)



Instructions for Use Hemlibra 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** 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, transfer needles, and injection needles that your healthcare provider prescribes.**
- **Use the syringes, transfer needles 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, injection needle and syringe dry.

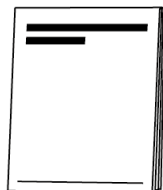
Inspecting the medicine and your supplies:

- 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:

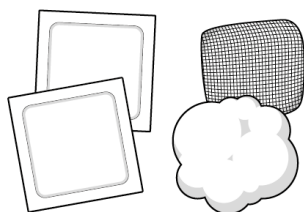


- **Vial containing the medicine**



- **HEMLIBRA Instructions for Use**

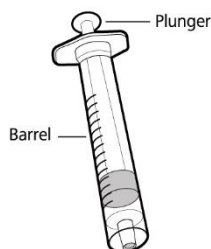
NOT INCLUDED IN THE BOX:



- **Alcohol wipes**

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.

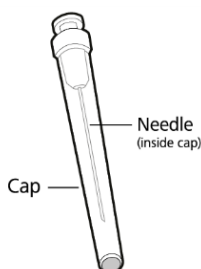
- **Gauze**
- **Cotton Ball**



- **Syringe**

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

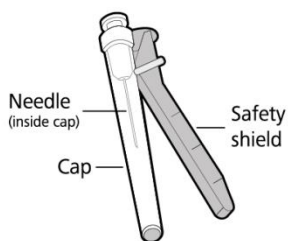
For injection amount between 1 mL and 2 mL use a **2 mL or 3 mL syringe**.



- **18G Transfer Needle**

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

Do not use the transfer needle to inject the medicine.



- **26G Injection Needle with safety shield**

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



- **Sharps disposal container**

Get ready:

- 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.

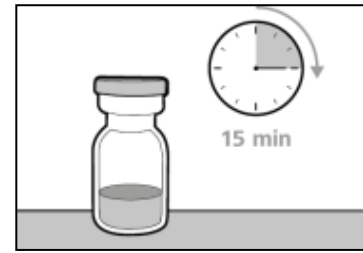


Figure A

Selecting and preparing an injection site:

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

For injection, you can use your:

- Thigh (front and middle).
- Stomach area (abdomen), except for 5 cm around the navel (belly button).
- Outer area of the upper arm (only if a caregiver is giving the injection).
- You should use a different injection site for each injection, at least 2.5 cm away from the area you used for your previous injection.
- Do not inject into areas that could be irritated by a belt or waistband. Do not inject into moles, scars, bruises, or areas where the skin is tender, red, hard or the skin is broken.

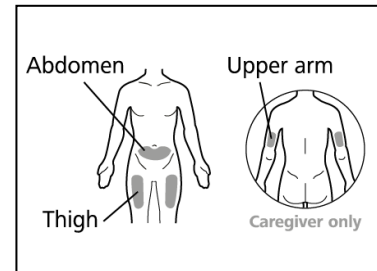


Figure B

Preparing the syringe for injection:

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

Important information after the injection:

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

Disposing of the medicine and supplies:**Important: Always keep the sharps disposal container out of reach of children.**

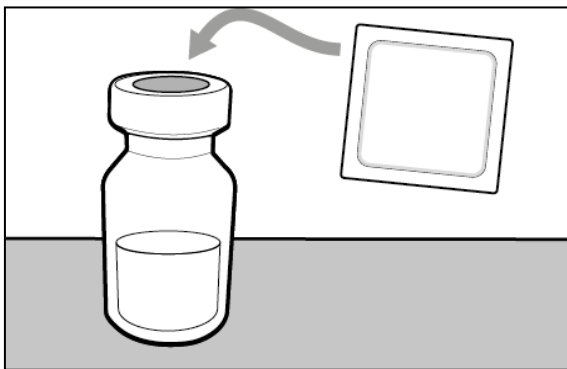
- Put your used needles and syringes in a sharps disposal container straight away after use. Do not throw away any loose needles and syringes in your household waste.
- If you do not have a sharps disposal container, you may use a household container that is:
 - made of heavy-duty plastic.
 - can be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

1. PREPARATION

Step 1. Remove vial cap and clean top

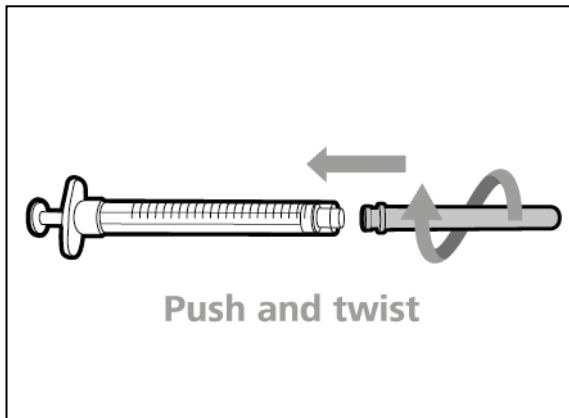


- Take the cap off the vial(s).
- Throw away the vial cap(s) into the sharps disposal container.

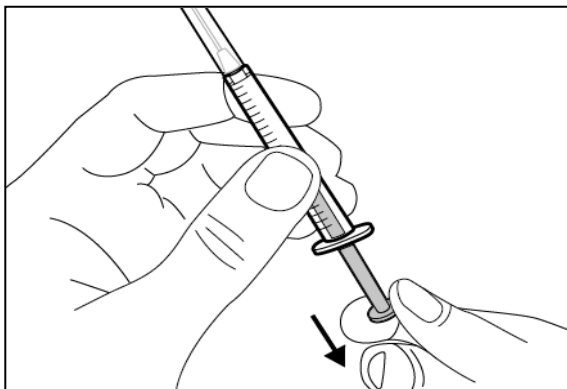


- Clean the top of the vial(s) stopper with an alcohol wipe.

Step 2. Attach transfer needle to syringe

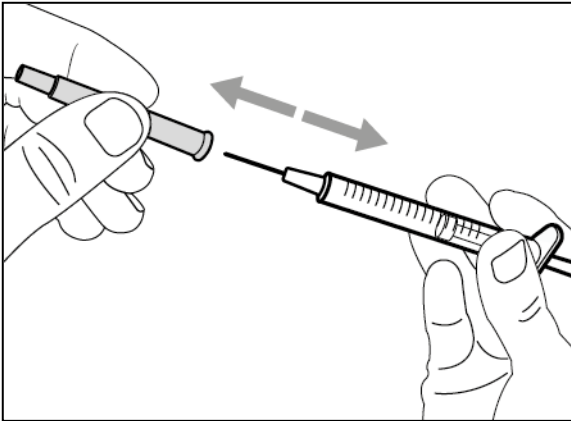


- **Push and twist the transfer needle clockwise** on to the syringe until it is fully attached.



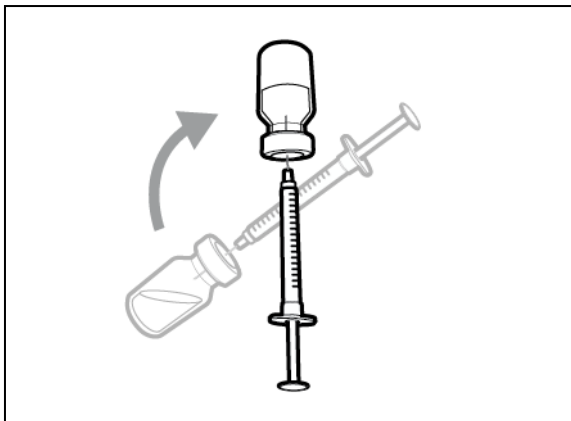
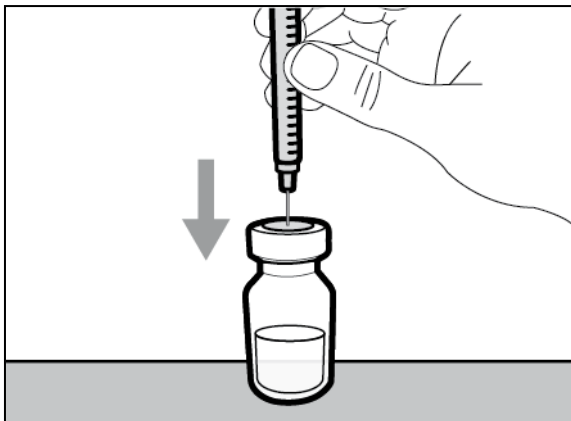
- Slowly pull back on the plunger and draw air into the syringe that is the same amount as your prescribed dose.

Step 3. Uncap transfer needle

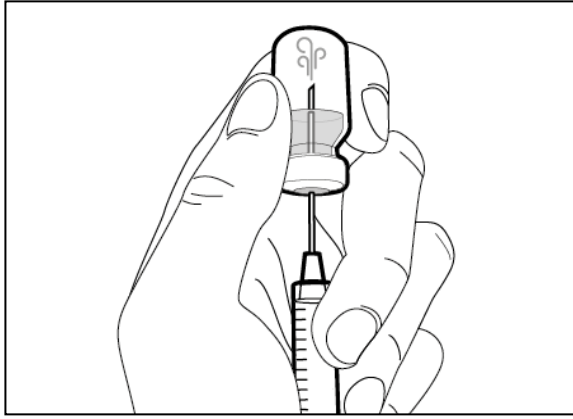


- Hold the syringe by the barrel with the transfer needle pointing up.
- Carefully pull the transfer needle cap straight off and away from your body. **Do not throw the cap away. Place the transfer needle cap down on a clean flat surface.** You will need to recap the transfer needle after transferring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

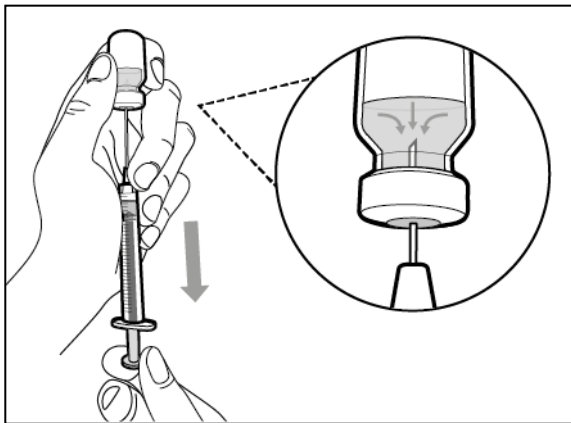


- Keep the vial on the flat working surface and insert the transfer needle and syringe straight down into the centre of the vial stopper.
- Keep the needle in the vial and turn the vial upside down.



- 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.

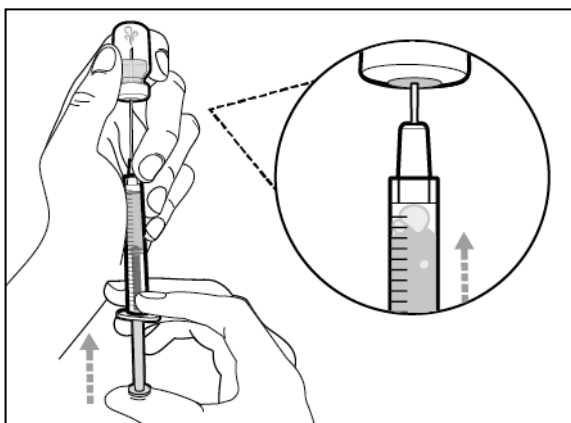
Step 5. Transfer medicine to syringe



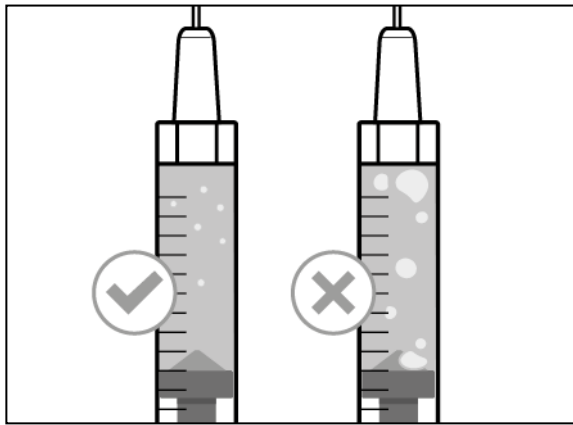
- Slide the tip of the needle down so that it is **within the medicine**.
- Slowly pull back the plunger to fill the syringe with more than the amount of medicine needed for your prescribed dose.
- Be careful not to pull the plunger out of the syringe.

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. 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.

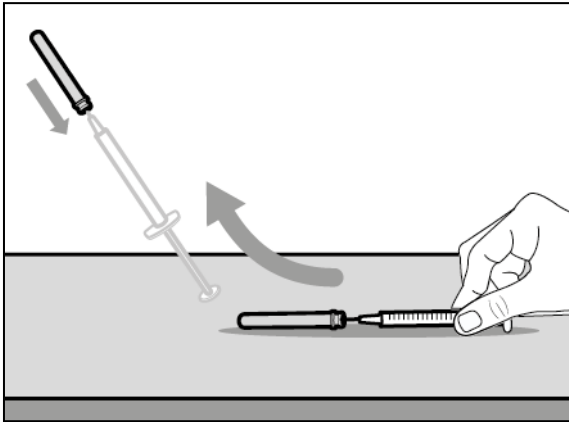
Note: Ensure you have enough medicine in the syringe to complete your dose before moving onto the next step. If you cannot remove all medicine, turn the vial upright to reach the remaining amount



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

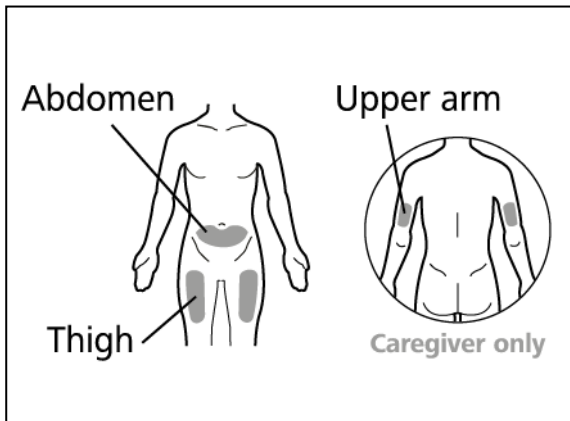
2. INJECTION

Step 7. Recap transfer needle



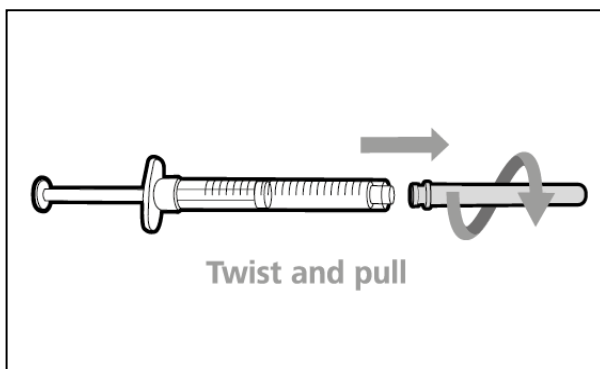
- Remove the syringe and transfer needle from the vial.
- **Using one hand, slide** the transfer needle into the cap and **scoop upwards** to cover the needle.
- Once the needle is covered, push the transfer needle cap towards the syringe to fully attach it with **one hand** to prevent accidentally injuring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

Step 8. Clean injection site



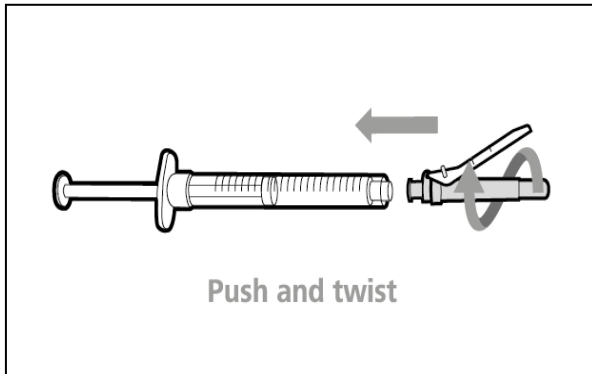
- Select and **clean** your injection site with an alcohol wipe.

Step 9. Remove transfer needle



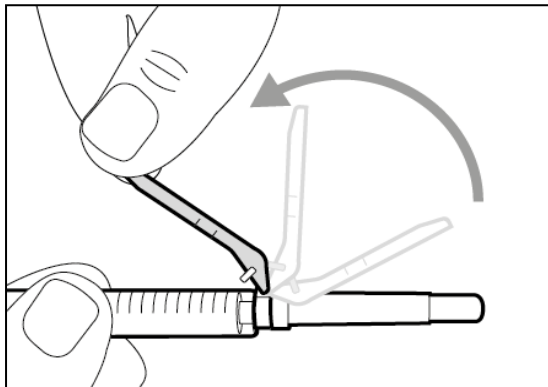
- Remove the transfer needle from the syringe by twisting anticlockwise and gently pulling.
- Throw away the used transfer needle into a sharps disposal container.

Step 10. Attach injection needle to syringe



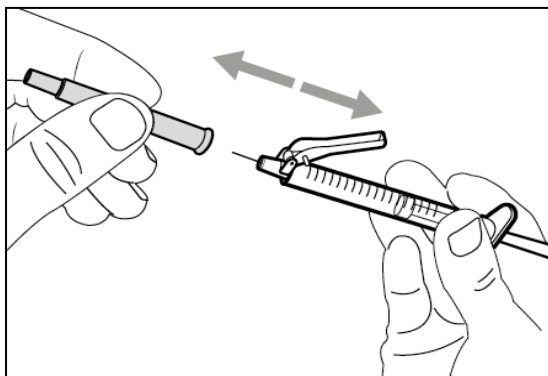
- Push and twist the injection needle clockwise onto the syringe until it is fully attached.

Step 11. Move safety shield



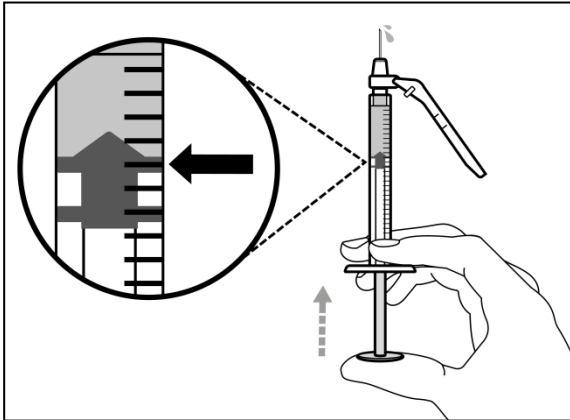
- Move the safety shield away from the needle and **towards** the syringe barrel.

Step 12. Uncap injection needle



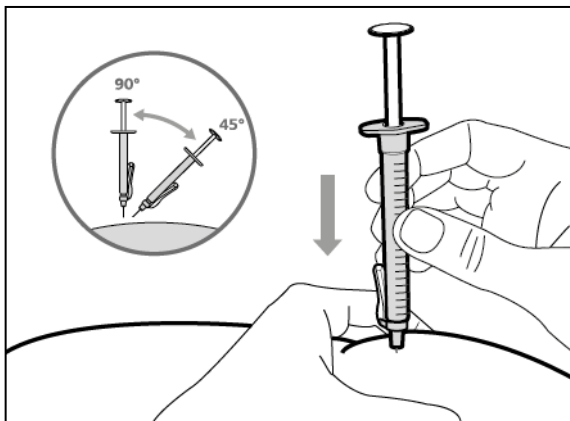
- **Carefully** pull the injection needle cap straightaway from the syringe.
- Throw away the cap into a sharps disposal container.
- **Do not touch** the needle tip or allow it to touch any surface.
- After the injection needle cap has been removed, the medicine in the syringe must be injected within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

Step 13. Adjust plunger to prescribed dose



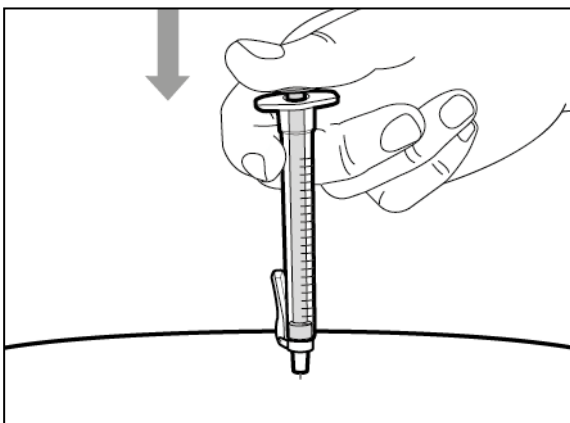
- Hold the syringe with the needle pointing up and slowly push the plunger to your prescribed dose.
- **Check your dose**, ensure the top rim of the plunger is in line with the mark on the syringe for your prescribed dose.

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.

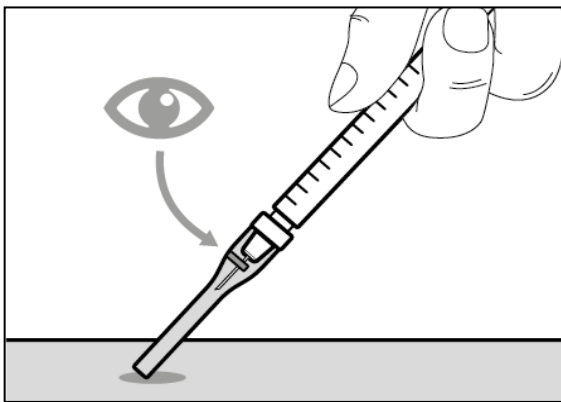
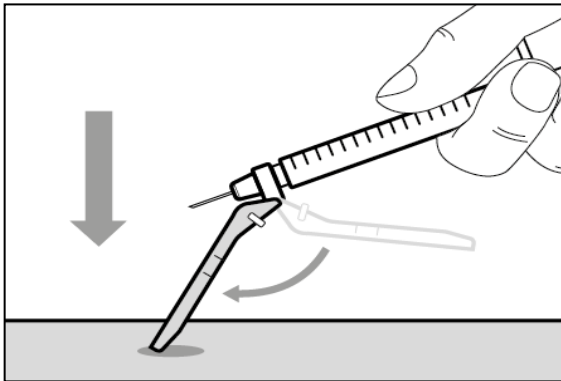
Step 15. Inject the medicine



- 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

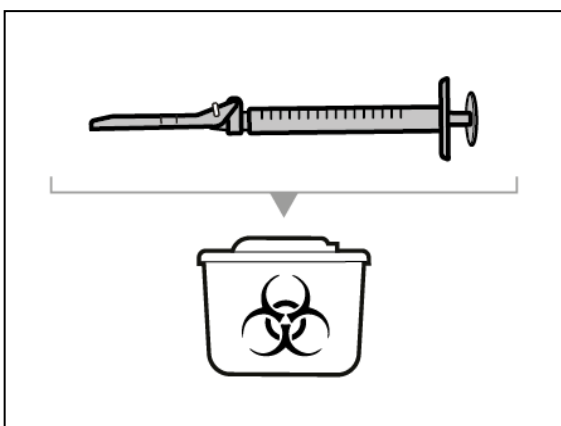
Step 16. Cover needle with safety shield



- 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.

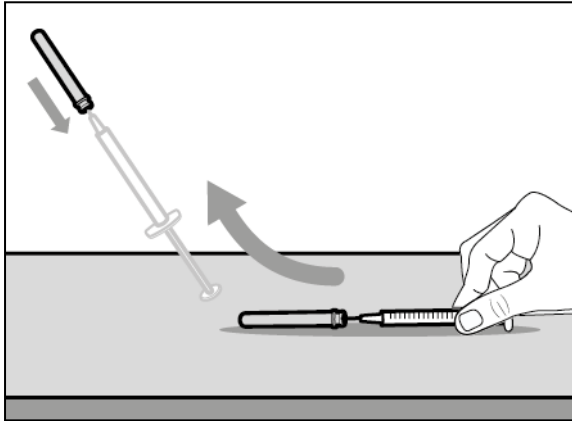


- Put **your** used needles and syringes in a sharps disposal container right away after use. For further information refer to the section “Disposing of the medicine and supplies”.
- **Do not** try to remove the used injection needle from the used syringe.
- **Do not recap** the injection needle with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

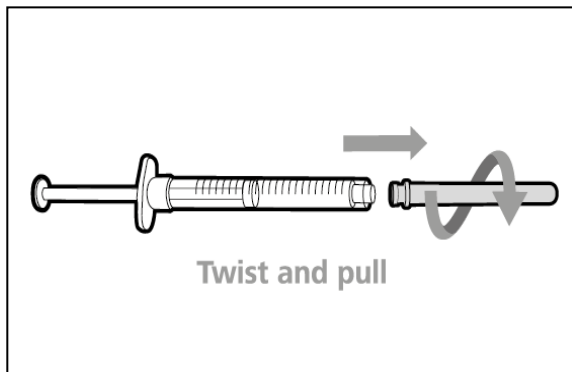
If you need to use more than 1 vial to get to your prescribed dose, follow these steps after you have drawn up the medicine from the first vial:

Step A. Recap transfer needle



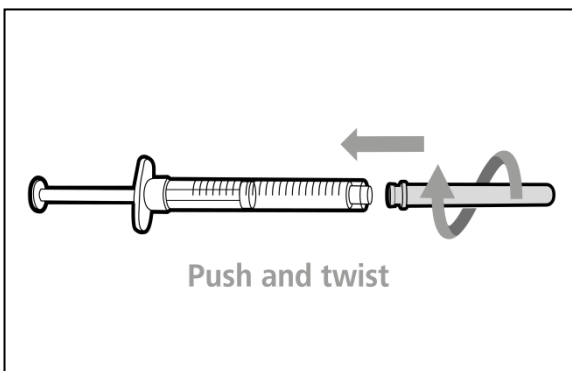
- Remove the syringe and transfer needle from the first vial.
- **Using one hand**, slide the transfer needle into the cap and **scoop upwards** to cover the needle.
- Once the needle is covered, push the transfer needle cap toward the syringe to fully attach it with **one hand** to prevent accidentally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

Step B. Remove transfer needle



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

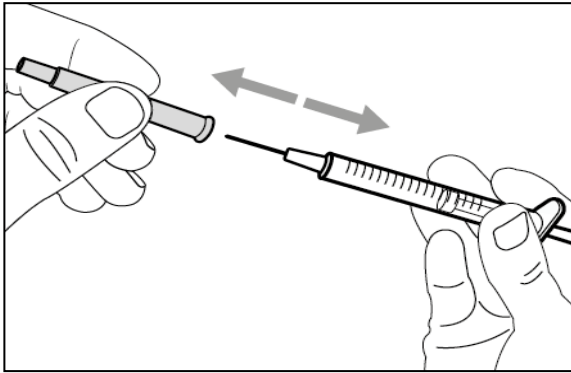
Step C. Attach a new transfer needle to syringe



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

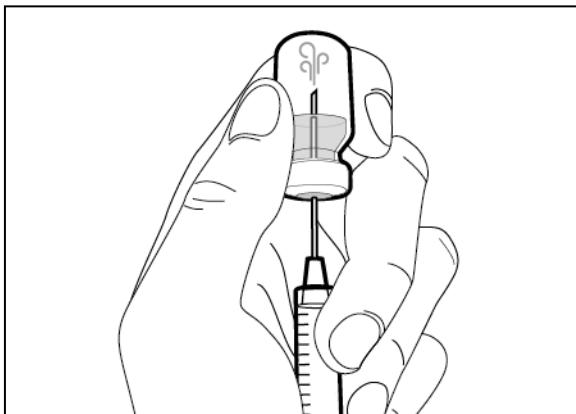
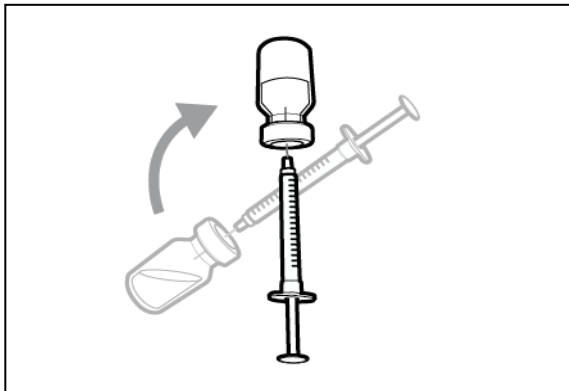
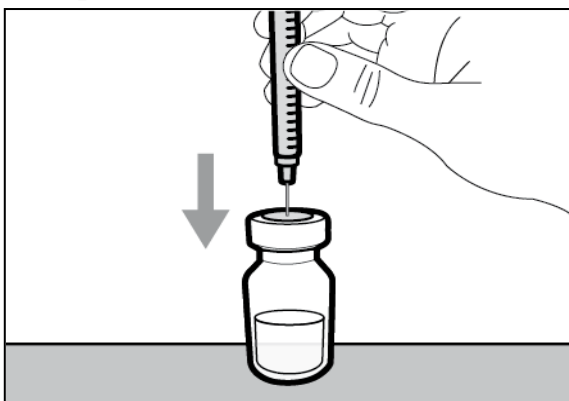
- Push and twist a **new** transfer needle clockwise on to the syringe until it is fully attached.
- Slowly pull back the plunger and draw some air into the syringe.

Step D. Uncap transfer needle



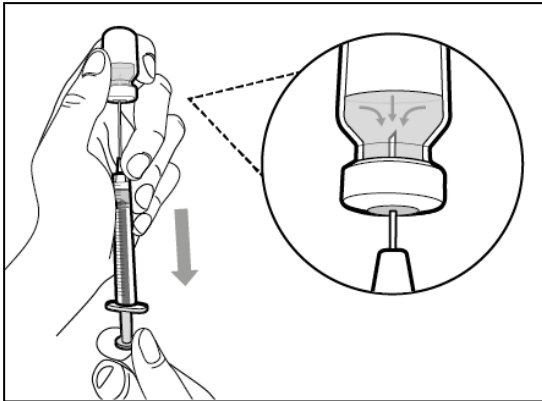
- Hold the syringe by the barrel with the transfer needle cap pointing up.
- Carefully pull the transfer needle cap straight off and away from your body. **Do not throw the cap** away. You will need to recap the transfer needle after drawing up the medicine.
- **Do not touch** the needle tip.

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 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 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.

Vial Adapter

Option

(For transfer of medicine from vial to syringe)



Instructions for Use
Hemlibra
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 transfer needle to withdraw Hemlibra from vial. These instructions are for use with the Vial Adapter 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 adapters, and injection needles that your healthcare provider prescribes.**
- **Use the syringes, vial adapters 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 adapters, needles and syringes:

- Keep the vial in the original box to protect the medicine from light.
- Keep vials, vial adapters, 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 adapter, injection needle and syringe dry.

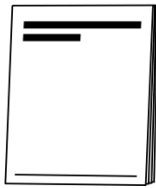
Inspecting the medicine and your supplies:

- 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:

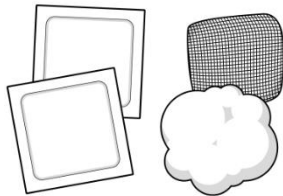


- **Vial containing the medicine**



- **HEMLIBRA Instructions for Use**


Not included in the box:

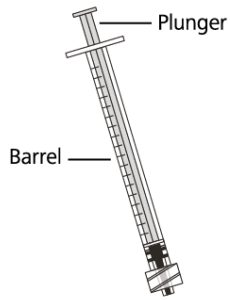


- **Alcohol wipes**
Note: If you need to use more than 1 vial to inject your prescribed dose, you must use a new alcohol wipe for each vial.
- **Gauze**
- **Cotton ball**



- **Vial adapter** (To be added on top of vial).
Note: Used for withdrawing medicine from the vial to the syringe. If you need to use more than 1 vial to inject your prescribed dose, you must use a new vial adapter for each vial.

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

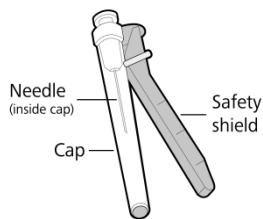


- **Syringe with Low Dead Space (LDS) Plunger**

- **Important:**

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

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



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

Do not insert the injection needle into vial adapter or use the injection needle to withdraw medicine from vial.



- **Sharps disposal container**

Get ready:

- 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.

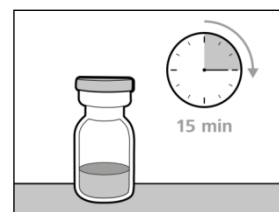


Figure A

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.

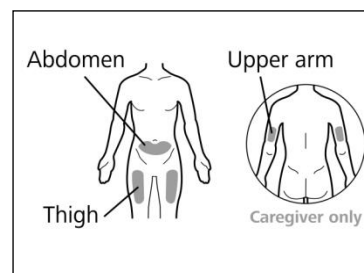


Figure B

For 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.

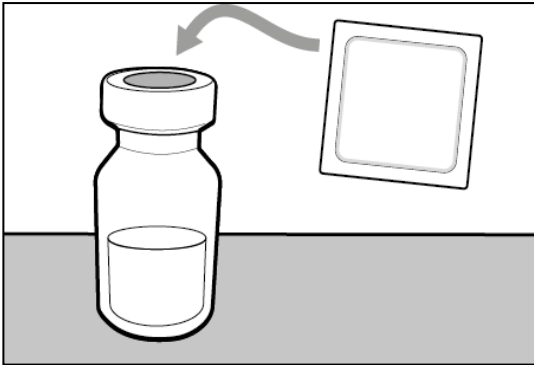
- **Throw away any used caps, vial(s), vial adapters, needles and syringes in a sharps or puncture-proof container.**
- Put your used vial adapters, needles and syringes in a sharps disposal container straight away after use. Do not throw away any loose caps, vials, needles and syringes in your household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

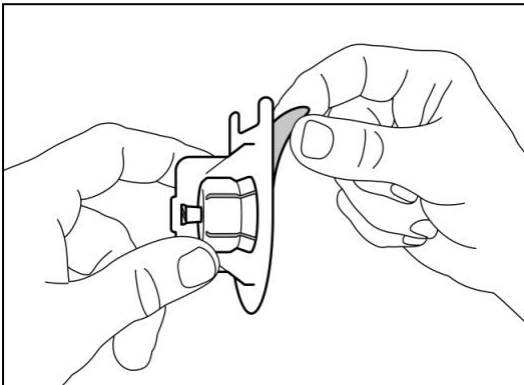


- Take the cap off the vial(s).
- Throw away the vial cap(s) into the sharps disposal container.



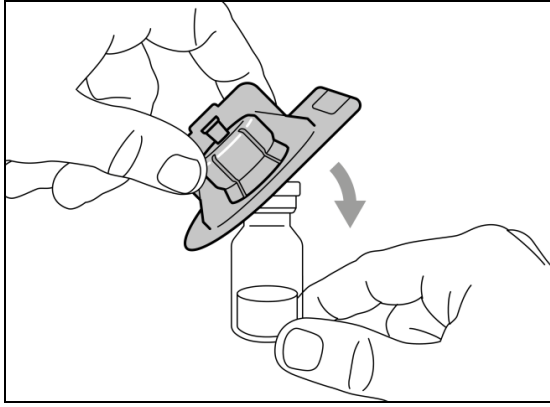
- Clean the top of the vial(s) stopper with an alcohol wipe.

Step 2. Insert vial adapter onto vial

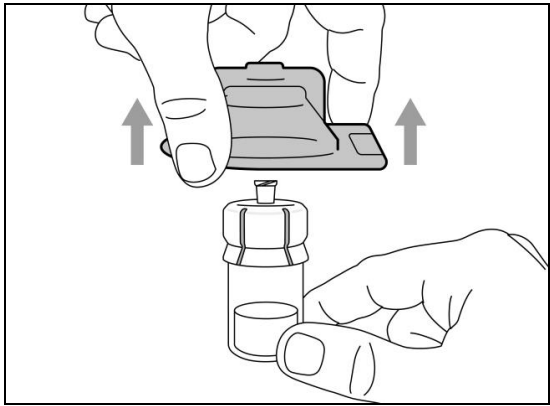


- Peel off back to open the blister pack.

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

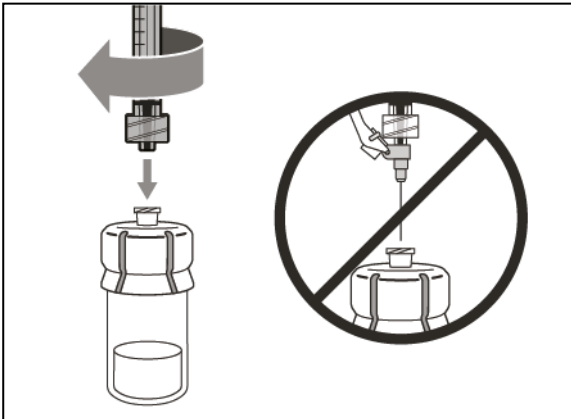


- Firmly press down the plastic blister pack with the vial adapter onto the new vial at an angle, until you hear a “click”.



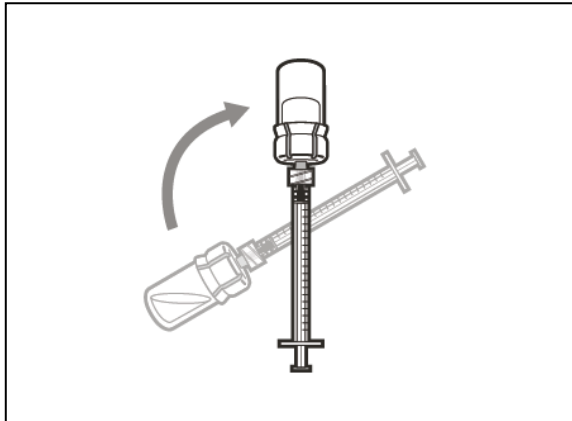
- Remove and throw away the plastic blister pack.
- **Do not** touch the tip of vial adapter.

Step 3. Connect syringe to vial adapter

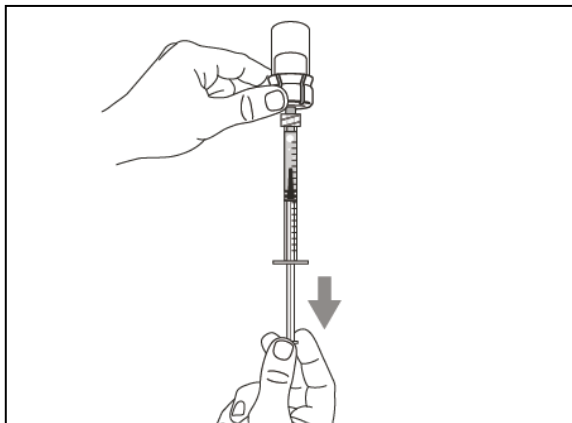


- **Remove syringe cap** (if required).
- **Push and twist the syringe clockwise** on to the vial adapter until it is fully attached.

Step 4. Transfer medicine to syringe



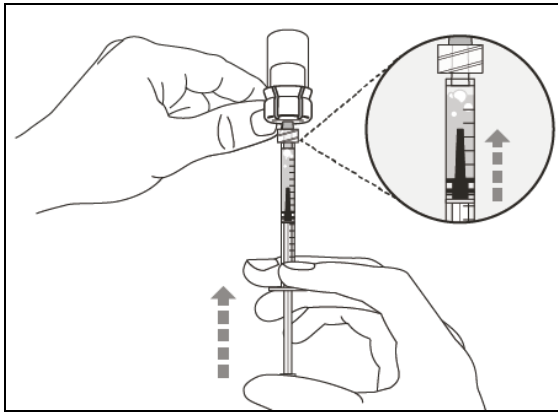
- Keep the vial adapter attached to the syringe and turn the vial upside down.



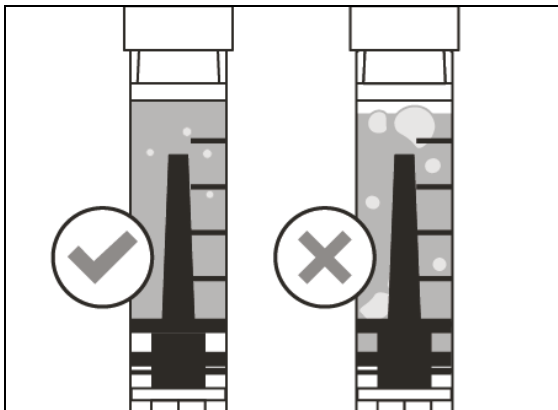
- With the syringe pointing upwards, slowly pull back the plunger to **fill the syringe with more than the amount of medicine** needed for your prescribed dose.
- **Hold plunger firmly** to ensure it does not pull back in.
- Be careful not to pull the plunger out of the syringe.

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.

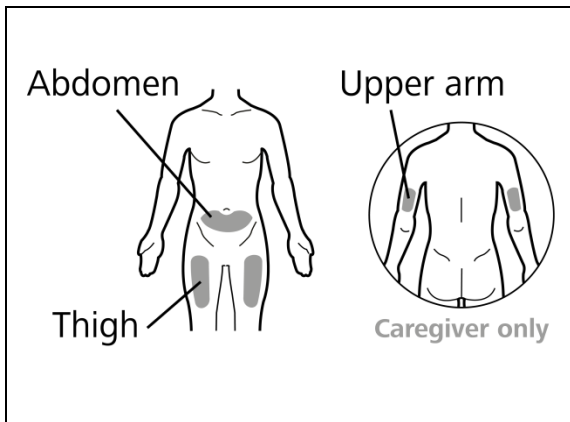


- **Remove the larger air bubbles** by gently **tapping** the syringe barrel with your finger until the air bubbles rise to the top of the syringe. **Slowly push the plunger** to push the large air bubbles out of the syringe.
- If the amount of medicine in the syringe is now at or below your prescribed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

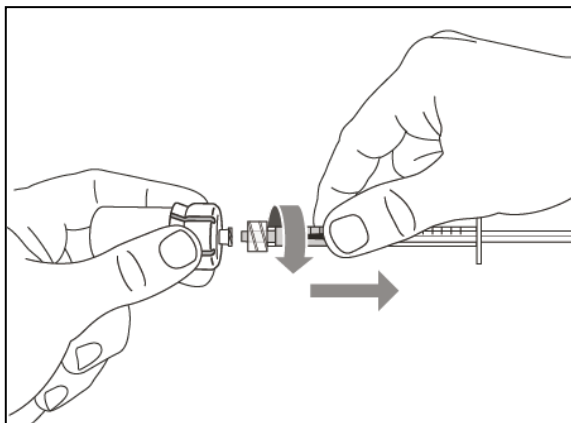
2.INJECTION

Step 6. Clean injection site



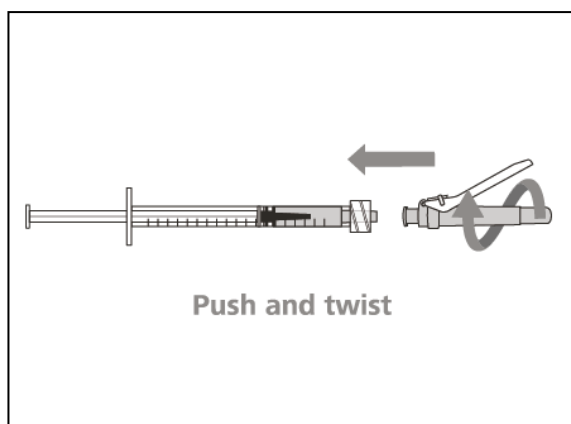
- Select and **clean** your injection site with an alcohol wipe.

Step 7. Remove syringe from vial adapter



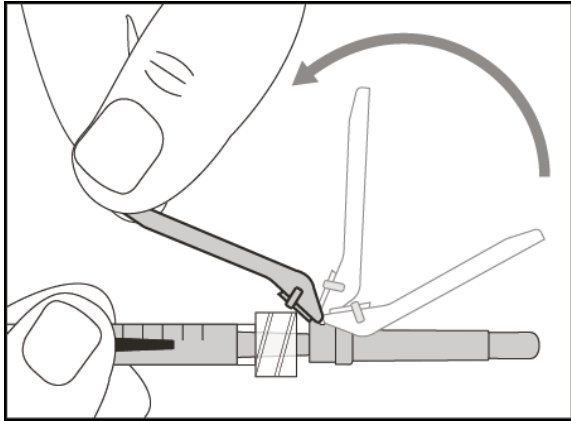
- Remove the syringe from the vial adapter by twisting anticlockwise and gently pulling.
- Throw away the used vial/vial adapter into a sharps disposal container.

Step 8. Attach injection needle to syringe



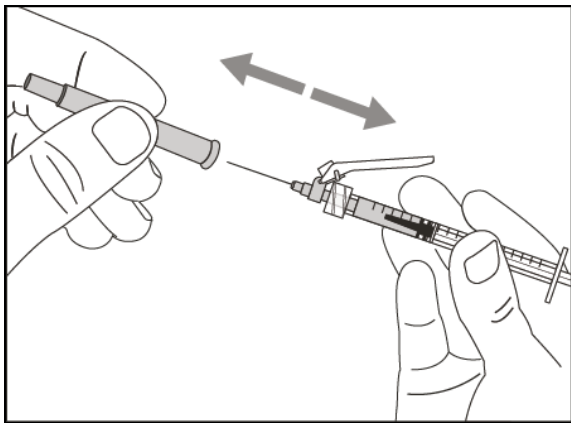
- Push and twist the injection needle clockwise onto the syringe until it is fully attached.
- **Do not** insert the injection needle into vial adapter or use the injection needle to withdraw medicine from vial.

Step 9. Move safety shield



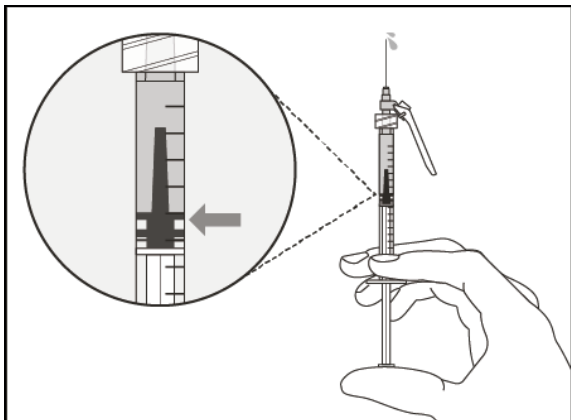
- Move the safety shield away from the needle and **towards** the syringe barrel.

Step 10. Uncap injection needle



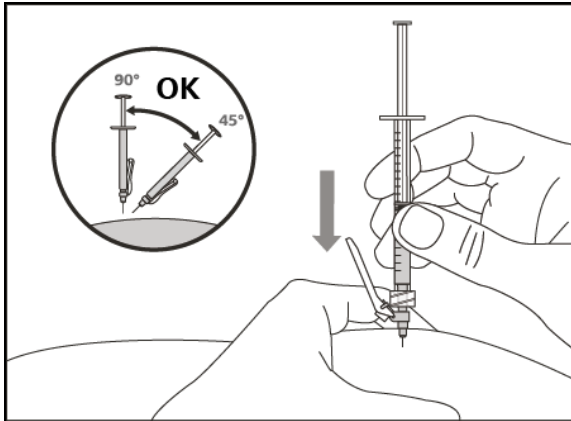
- **Carefully** pull the injection needle cap **straightaway** from the syringe.
- Throw away the cap into a sharps disposal container.
- **Do not touch** the needle tip or allow it to touch any surface.
- After the injection needle cap has been removed, the medicine in the syringe must be injected within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

Step 11. Adjust plunger to prescribed dose



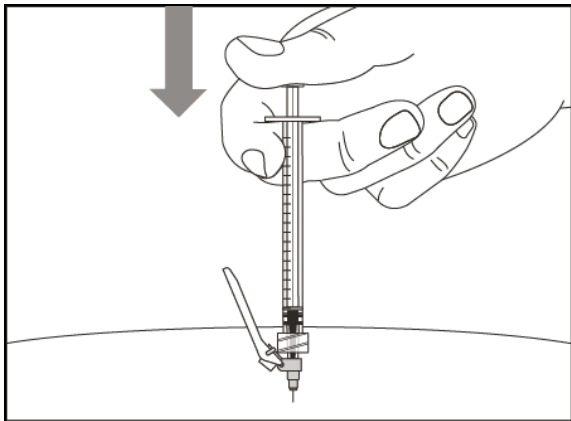
- Hold the syringe with the needle pointing up and slowly push the plunger to your prescribed dose.
- **Check your dose**, ensure the top rim of the plunger is in line with the mark on the syringe for your prescribed dose.

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.

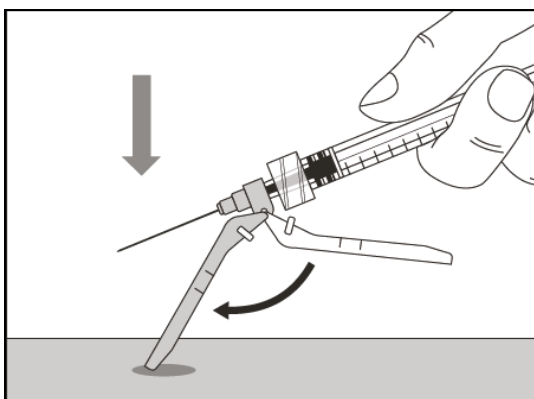
Step 13. Inject the medicine



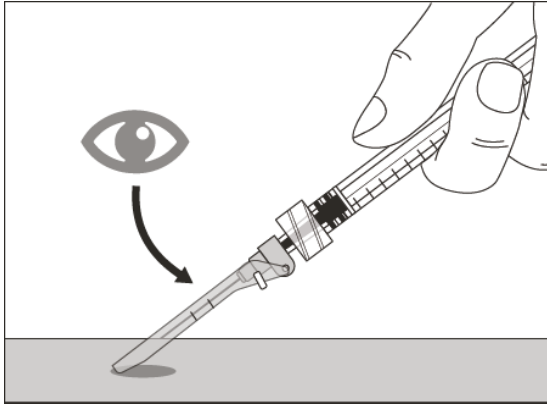
- Slowly inject all of the medicine by gently pushing the plunger all the way down.
- Remove the needle and syringe from the injection site at the same angle as inserted.

3.DISPOSAL

Step 14. Cover needle with safety shield

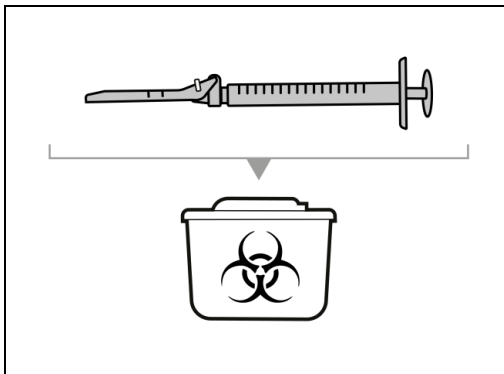


- Move the safety shield forward 90°, away from the syringe barrel.
- **Holding the syringe with one hand, press the safety shield down** against a flat surface with a firm, quick motion until you hear a “click”.



- 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

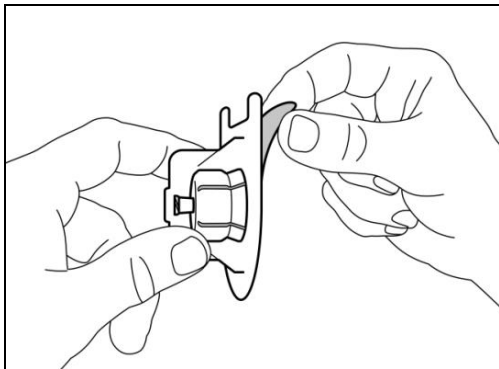


- Put your used needles and syringes in a sharps disposal container right away after use. For further information refer to the section “Disposing of the medicine and supplies”.
- **Do not** try to remove the used injection needle from the used syringe.
- **Do not recap** the injection needle with the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

Combining Vials

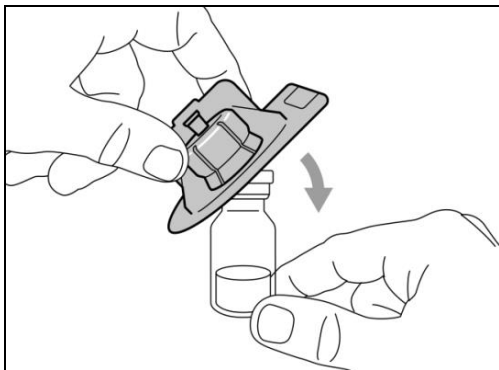
If you need to use more than 1 vial to get to your prescribed dose, follow these steps after you have drawn up the medicine from the first vial:

Step A. Insert new vial adapter into new vial

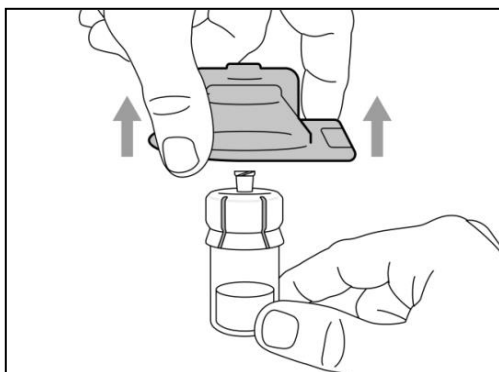


- Peel off back to open the blister pack.

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

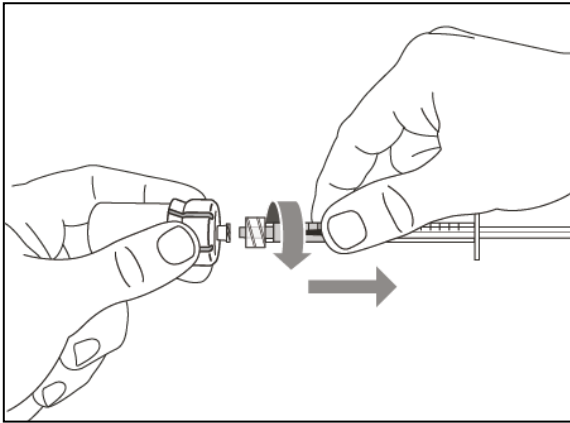


- Firmly press down the plastic blister pack with the vial adapter onto the new vial at an angle, until you hear a **'click'**.



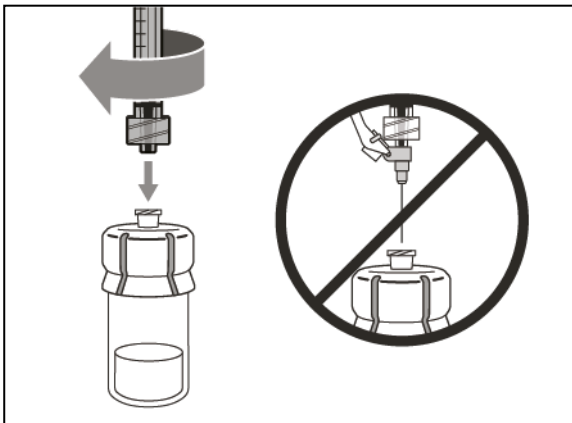
- Remove and throw away the plastic blister pack.
- **Do not** touch the tip of vial adapter.

Step B. Remove used vial adapter



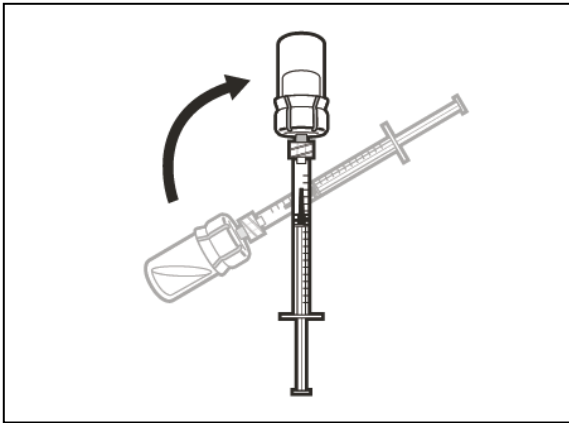
- Remove the used vial adapter from the syringe by twisting anticlockwise and gently pulling.
- Throw away the used vial/vial adapter into a sharps disposal container.

Step C. Connect new vial adapter to syringe

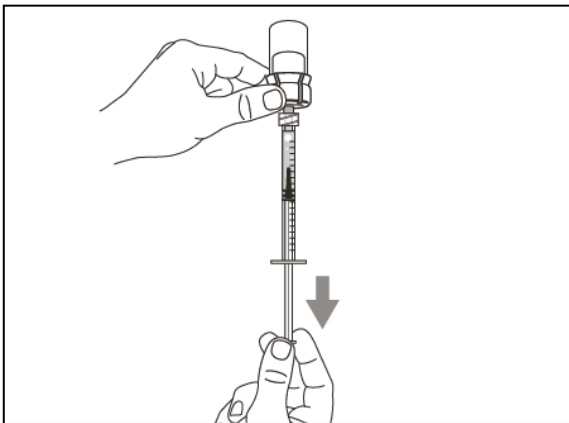


- **Push and twist the syringe clockwise** on to the vial adapter until it is fully attached.

Step D. Transfer medicine into syringe



- Keep the vial adapter 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 adapter onto the vial and return to Step 5 “Remove air bubbles”. Continue with the remaining steps.