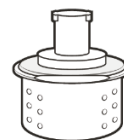


HEMLIBRA VIAL ADAPTER USAGE GUIDE

(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 the 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, NEEDLES AND SYRINGES:

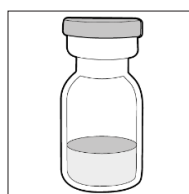
- Keep the vial in the original box to protect the medicine from light.
- Keep the vials, needles and syringes out of the sight and reach of children.
- Store the vial in the refrigerator (2°C to 8°C).

- **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 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 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 vials adapter, injection needle and syringe dry.

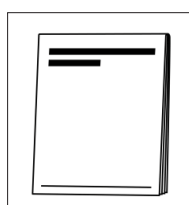
INSPECTING THE MEDICINE AND YOUR SUPPLIES:

- 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:

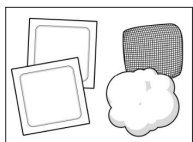


- Vial containing the medicine

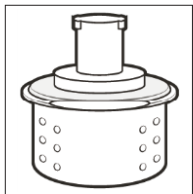


- Instructions for Use

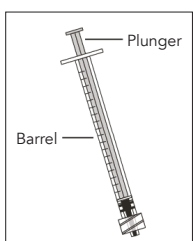
NOT INCLUDED IN THE BOX:



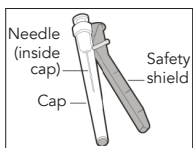
- **Alcohol wipes**
Note: If you need to use more than 1 vial to inject your prescribed dose, you must use a new alcohol wipe for each vial.
- **Gauze**
- **Cotton ball**



- **Vial adapter** (To be added on top of the 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 the vial adapter.**



- **Syringe with Low Dead Space (LDS) Plunger**
Important:
 - For injection amount up to 1 mL use **1 mL LDS syringe**.
 - For injection amount over 1 mL use **2 or 3 mL LDS syringes**.**Note:** Do not use 2 or 3 mL LDS syringes 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.



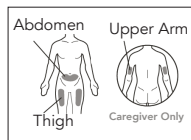
- **Sharps disposal container**

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.

SELECTING AND PREPARING AN INJECTION SITE:



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

FOR YOUR INJECTION, YOU CAN USE YOUR:

- Thigh (front and middle).
- Stomach area (abdomen), except for 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 any 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:

- 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** touch exposed needles or place them on a surface once the cap has been removed.
- **Do not** use the syringe if the needle touches any surface.

IMPORTANT INFORMATION AFTER THE 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.
- **Do not** rub the injection site after injection.

DISPOSING OF THE MEDICINE AND SUPPLIES:

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

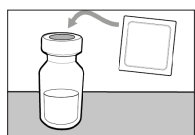
- Throw away any used caps, vial(s), vial adapters, needles and syringes in a sharps or puncture-proof container.
- Put your used vial adapters, needles and syringes in a sharps disposal container straight away after use. Do not throw away any loose caps, vials, needles and syringes in your household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

PREPARATION:

STEP 1. REMOVE VIAL CAP AND CLEAN TOP

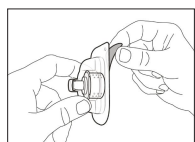


- Take the cap off the vial(s).
- Throw away the vial cap(s) into the sharps disposal container.

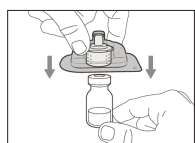


- Clean the top of the vial(s) stopper with an alcohol wipe.

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.

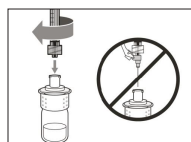


- Firmly press down the plastic blister pack with the vial adapter onto the new vial, until you hear a “click”.



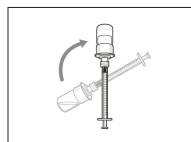
- Remove and throw away the plastic blister pack.
- **Do not** touch the tip of vial adapter.

STEP 3. CONNECT SYRINGE TO VIAL ADAPTER

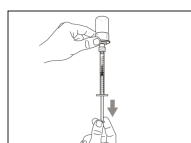


- Remove syringe cap (if required).
- Push and twist the syringe clockwise on to the vial adapter until it is fully attached.

STEP 4. TRANSFER MEDICINE TO SYRINGE



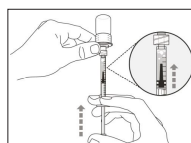
- Keep the vial adapter attached to the syringe and turn the vial upside down.



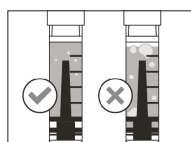
- With the syringe pointing upwards, slowly pull back the plunger to **fill the syringe with more than the amount of medicine** needed for your prescribed dose.
- **Hold plunger firmly** to ensure it does not pull back in.
- Be careful not to pull the plunger out of the syringe.

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.

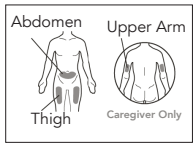


- Remove the larger air bubbles by gently **tapping** the syringe barrel with your finger until the air bubbles rise to the top of the syringe. **Slowly push the plunger** to push the large air bubbles out of the syringe.
- If the amount of medicine in the syringe is now at or below your prescribed dose,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

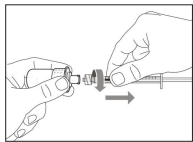
INJECTION:

STEP 6. CLEAN INJECTION SITE



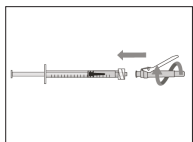
- Select and **clean** your injection site with an alcohol wipe.

STEP 7. REMOVE SYRINGE FROM VIAL ADAPTER



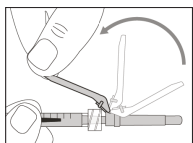
- Remove the syringe from the vial adapter by twisting anticlockwise and gently pulling.
- Throw away the used vial/vial adapter into a sharps disposal container.

STEP 8. ATTACH INJECTION NEEDLE TO SYRINGE



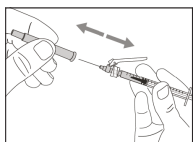
- Push and twist the injection needle clockwise onto the syringe until it is fully attached.
- **Do not** insert the injection needle into vial adapter or use the injection needle to withdraw medicine from vial.

STEP 9. MOVE SAFETY SHIELD



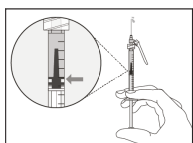
- Move the safety shield away from the needle and towards the syringe barrel.

STEP 10. UNCAP INJECTION NEEDLE



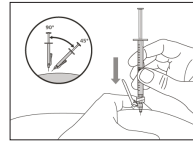
- **Carefully** pull the injection needle cap straightaway from the syringe.
- Throw away the cap into a sharps disposal container.
- **Do not** touch the needle tip or allow it to touch any surface.
- After the injection needle cap has been removed, the medicine in the syringe must be injected within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

STEP 11. ADJUST PLUNGER TO PRESCRIBED DOSE



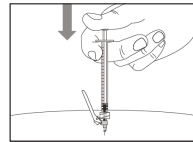
- Hold the syringe with the needle pointing up and slowly push the plunger to your prescribed dose.
- **Check your dose**, ensure the top rim of the plunger is in line with the mark on the syringe for your prescribed dose.

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.

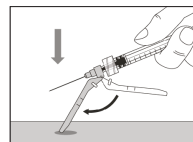
STEP 13. INJECT THE MEDICINE



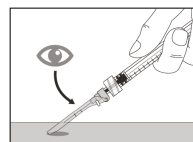
- Slowly inject all of the medicine by gently pushing the plunger all the way down.
- Remove the needle and syringe from the injection site at the same angle as inserted.

DISPOSAL:

STEP 14. COVER NEEDLE WITH SAFETY SHIELD

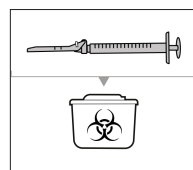


- Move the safety shield forward 90°, away from the syringe barrel.
- **Holding the syringe with one hand, press the safety shield down** against a flat surface with a firm, quick motion until you hear a “click”.



- 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

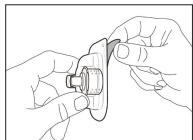


- Put your used needles and syringes in a sharps disposal container right away after use. For further information refer to the section “Disposing of the medicine and supplies”.
- **Do not** try to remove the used injection needle from the used syringe.
- **Do not** recap the injection needle with the 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 as described in step 4 "Transfer medicine to syringe". You must use a new vial adapter for each vial.

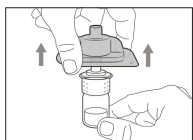
STEP A. INSERT NEW VIAL ADAPTER INTO NEW VIAL



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

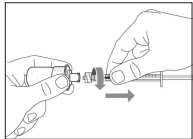


- Firmly press down the plastic blister pack with the vial adapter onto the new vial, until you hear a "click".



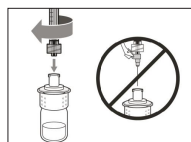
- Remove and throw away the plastic blister pack.
- **Do not** touch the tip of the vial adapter.

STEP B. REMOVE SYRINGE FROM USED VIAL ADAPTER



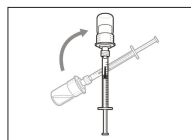
- Remove the syringe from the used vial adapter by twisting anticlockwise and gently pulling.
- Throw away the used vial/vial adapter into a sharps disposal container.

STEP C. CONNECT SYRINGE TO NEW VIAL ADAPTER

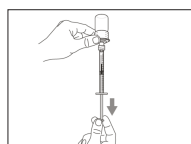


- **Push and twist the same syringe clockwise** on to the next vial adapter until it is fully attached.

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 on the vial and return to Step 5 "Remove air bubbles". Continue with the remaining steps.

Hemlibra® (emicizumab)

Hemlibra is a trademark of Hoffmann-La-Roche AG.

Roche Products (New Zealand) Limited
PO Box 109113 Newmarket
Auckland 1149
NEW ZEALAND

Medical enquiries: 0800 276 243



Hemlibra®(emicizumab), 30 mg in 1 mL, 60 mg in 0.4 mL, 105 mg in 0.7 mL and 150 mg in 1 mL ready-to-use solution for subcutaneous (SC) injection, is a **Prescription Medicine** used to prevent bleeding or reduce the frequency of bleeding in people with haemophilia A with or without factor VIII inhibitors

Ask your doctor if Hemlibra® is right for you.

HEMLIBRA is funded for patients with haemophilia A with inhibitors, who meet predefined criteria. From 1 October 2023 HEMLIBRA is also funded for people with haemophilia A, without inhibitors, who meet predefined criteria.

Use only as directed. If symptoms continue or you have side effects, see your healthcare professional.
For more information about Hemlibra®:

- talk to your health professional; or
- visit [medsafe.govt.nz](https://www.medsafe.govt.nz) for Hemlibra® Consumer Medicine Information; or
- visit [roche.co.nz](https://www. Roche.co.nz) or call Roche on 0800 276 243.

Hemlibra® has risks and benefits.

Possible common side effects include: injection site reactions, headache, joint pains, high temperature or fever, diarrhoea, muscle aches, hives (urticaria), rash; swollen lips, mouth, face, tongue and/or throat and/or difficulty in swallowing and breathing (angioedema)

Do not use Hemlibra® if: you have had an allergic reaction to HEMLIBRA or any of the ingredients, or to any medicines that are made using Chinese hamster ovary cells.

Tell your doctor if: you have allergies to any other medicines, foods, preservatives or dyes; you are taking bypassing agents or any other blood product; you are pregnant or plan to become pregnant or are breastfeeding; you are using any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice any of the following: confusion, weakness, swelling of arms and legs, yellowing of skin and eyes, abdominal or back pain, feeling sick (nausea), being sick (vomiting) or urinating less – may be signs of thrombotic microangiopathy (TMA); swelling, warmth, pain or redness – 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 – may be signs of a blood clot in a vein behind your eye; blackening of the skin – may be a sign of severe damage to the skin tissue; if it appears that HEMLIBRA is no longer working for you – an uncommon occurrence of antibody production against HEMLIBRA.

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The information contained in this brochure does not provide medical advice or take the place of speaking with your healthcare practitioner about your medical condition or treatment.

Please see the HEMLIBRA Consumer Medicines Information (CMI) on www.medsafe.govt.nz for Important Safety Information, including Serious Side Effects



Scan the QR
code to go to
Medsafe CMI

M-NZ-00001219/MR11441/FEB2025



HEMLIBRA®
emicizumab injection