



HEMLIBRA[®] injection single-dose vial(s)
(emicizumab)

INSTRUCTIONS FOR USE

This booklet is for patients who are treated with HEMLIBRA and their carers. The information in this guide is designed to help support the safe use of HEMLIBRA for the treatment of haemophilia A with or without factor VIII inhibitors.



You must read, understand and follow the Instructions for Use before injecting HEMLIBRA (emicizumab). 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 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 with filter, and injection needles that your healthcare provider prescribes.**
- **Use the syringes, transfer needles with filter and injection needles only once. Throw away used vials, syringes and needles in a sharps container. Speak to your healthcare professional to find out the best way to dispose of the sharps 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.
- **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 with filter, injection needle and syringe dry.

Inspecting the medicine and your supplies

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

INCLUDED IN YOUR MEDICINE:

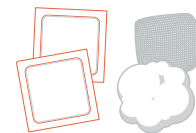


- **Vial containing the medicine**



- **Instructions for Use**

NOT INCLUDED IN YOUR MEDICINE:



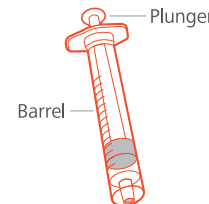
- **Alcohol wipes**
Note: If you need to use more than 1 vial to inject your prescribed dose, you must use a new alcohol wipe for each vial.

- **Gauze**

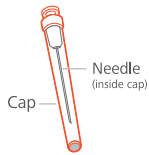
- **Cotton ball**

- **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**.



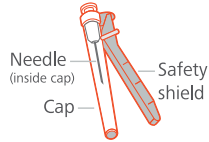
NOT INCLUDED IN YOUR MEDICINE:



- **18G Transfer needles with filter**

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

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



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

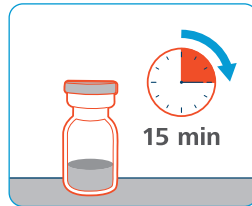
Do not use the injection needle to withdraw medicine from vial.



- **Sharps disposal container**

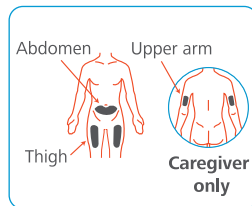
Get ready:

- 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.



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.



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 disposal 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 applied with gentle pressure on the site. If bleeding does not stop, please contact your healthcare provider.

Disposing of sharps

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

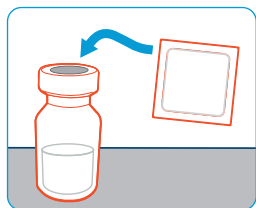
- Put your used needles and syringes in a sharps disposal container straight away after use. Do not throw away any loose needles and syringes in your household waste.
- When your sharps disposal container is almost full, you will need to follow your local guidelines or speak to your healthcare professional 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.



STEP 1. REMOVE VIAL CAP AND CLEAN TOP

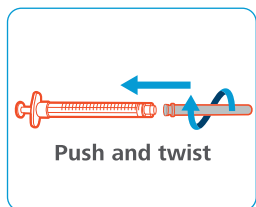


- Take the cap off the vial(s).
- Throw away the vial cap(s) into the sharps disposal container.

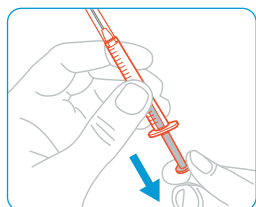


- Clean the top of the vial(s) stopper with an alcohol wipe.

STEP 2. ATTACH TRANSFER NEEDLE WITH FILTER TO SYRINGE

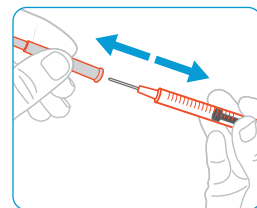


- **Push and twist the transfer needle with filter clockwise** on to the syringe until it is fully attached.



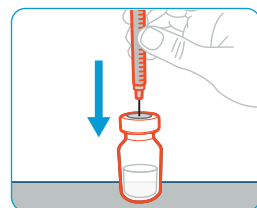
- Slowly pull back on the plunger and draw air into the syringe that is the same amount as your prescribed dose.

STEP 3. UNCAP TRANSFER NEEDLE WITH FILTER

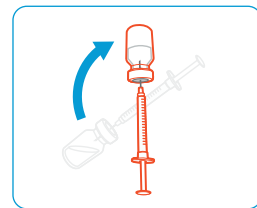


- Hold the syringe by the barrel with the transfer needle with filter pointing up.
- Carefully pull the transfer needle with filter cap straight off and away from your body. **Do not throw the cap away. Place the transfer needle with filter cap down on a clean flat surface.** You will need to recap the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

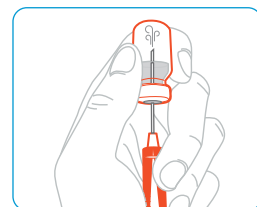
STEP 4. INJECT AIR INTO VIAL



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

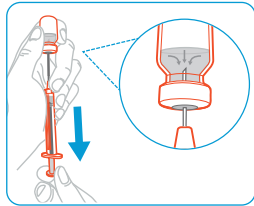


- Keep the needle in the vial and turn the vial upside down.



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

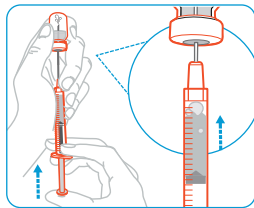
STEP 5. TRANSFER MEDICINE TO SYRINGE



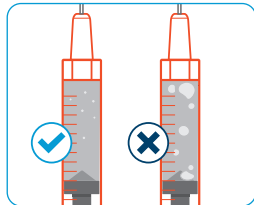
- Slide the tip of the needle down so that it is **within the medicine**.
- Slowly pull back the plunger to fill the syringe with more than the amount of medicine needed for your prescribed dose.
- Be careful not to pull the plunger out of the syringe.

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



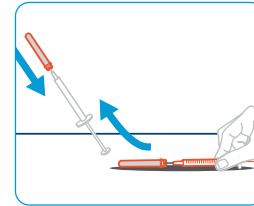
- If the amount of medicine in the syringe is now at or below your prescribed dose, move the tip of the needle to **within the medicine** and slowly **pull** back the plunger until you have **more** than the amount of medicine needed for your **prescribed dose**.
- Be careful not to pull the plunger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



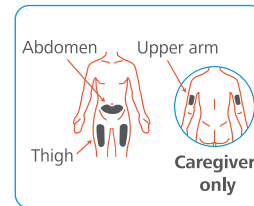
Do not use the transfer needle with filter to inject medicine as this may cause harm such as pain and bleeding.

STEP 7. RECAP TRANSFER NEEDLE WITH FILTER



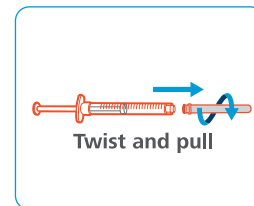
- Remove the syringe and transfer needle with filter from the vial.
- **Using one hand, slide** the transfer needle with filter into the cap and **scoop upwards** to cover the needle.
- Once the needle is covered, push the transfer needle with filter cap towards the syringe to fully attach it with **one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

STEP 8. CLEAN INJECTION SITE



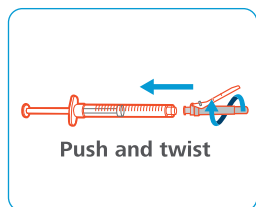
- Select and **clean** your injection site with an alcohol wipe.

STEP 9. REMOVE TRANSFER NEEDLE WITH FILTER



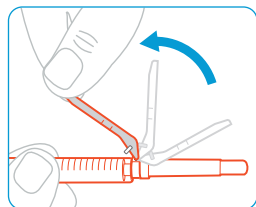
- Remove the transfer needle with filter from the syringe by twisting anti-clockwise and pulling gently.
- Throw away the used transfer needle with filter into a sharps disposal container.

STEP 10. ATTACH INJECTION NEEDLE TO SYRINGE



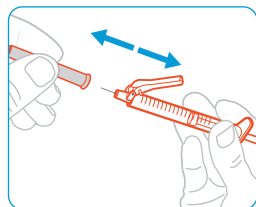
- Push and twist the injection needle clockwise onto the syringe until it is fully attached.

STEP 11. MOVE SAFETY SHIELD



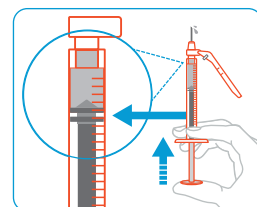
- Move the safety shield away from the needle and **towards** the syringe barrel.

STEP 12. UNCAP INJECTION NEEDLE



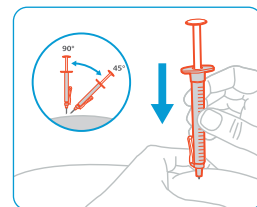
- **Carefully** pull the injection needle cap **away** from the syringe.
- Throw away the cap into a sharps disposal container.
- **Do not touch** the needle tip or allow it to touch any surface.
- After the injection needle cap has been removed, the medicine in the syringe must be injected within 5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

STEP 13. ADJUST PLUNGER TO PRESCRIBED DOSE



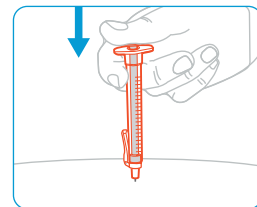
- Hold the syringe with the needle pointing up and slowly push the plunger to your prescribed dose.
- Ensure the top rim of the plunger is in line with the mark on the syringe for your prescribed dose.

STEP 14. SUBCUTANEOUS (UNDER THE SKIN) INJECTION



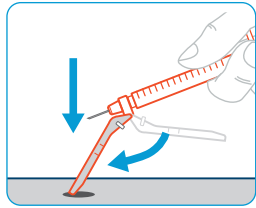
- Pinch the selected injection site and fully insert the needle at a **45° to 90° angle** with a quick, firm action. **Do not** hold or push on the plunger while inserting the needle.
- Hold the position of the syringe and let go of the pinched injection site.

STEP 15. INJECT THE MEDICINE

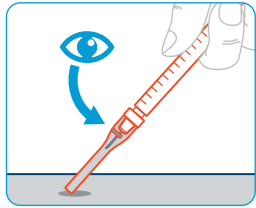


- Slowly inject all of the medicine by gently pushing the plunger all the way down.
- Remove the needle and syringe from the injection site at the same angle as inserted.

STEP 16. COVER NEEDLE WITH SAFETY SHIELD

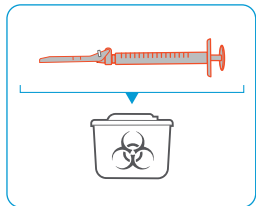


- Move the safety shield forward 90°, away from the syringe barrel.
- Holding the syringe with one hand, **press the safety shield down** against a flat surface with a firm, quick motion until you hear a "click".



- 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.

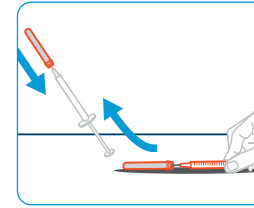
STEP 17. THROW AWAY THE SYRINGE AND NEEDLE



- Put your used needles and syringes 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.

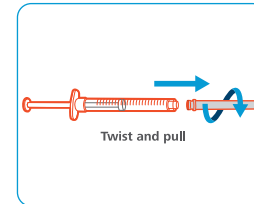
If you need to use more than 1 vial to get to your total prescribed dose, follow these steps after you have drawn up the medicine from the first vial.

STEP A. RECAP TRANSFER NEEDLE WITH FILTER



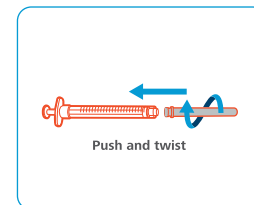
- Remove the syringe and transfer needle with filter from the first vial.
- **Using one hand**, slide the transfer needle with filter into the cap and **scoop upwards** to cover the needle.
- Once the needle is covered, push the transfer needle with filter cap toward the syringe to fully attach it with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

STEP B. REMOVE TRANSFER NEEDLE WITH FILTER



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

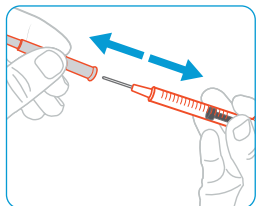
STEP C. ATTACH A NEW TRANSFER NEEDLE WITH FILTER TO SYRINGE



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

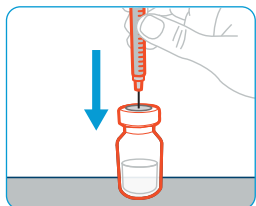
- Push and twist a **new** transfer needle with filter clockwise on to the syringe until it is fully attached.
- Slowly pull back the plunger and draw some air into the syringe.

STEP D. UNCAP TRANSFER NEEDLE WITH FILTER

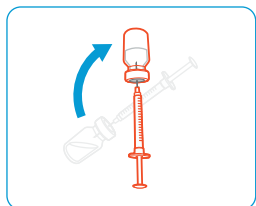


- Hold the syringe by the barrel with the transfer needle with filter pointing up.
- Carefully pull the transfer needle with filter cap straight off and away from your body. Do not throw the cap away. You will need to recap the transfer needle with filter after drawing up the medicine.
- **Do not touch**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

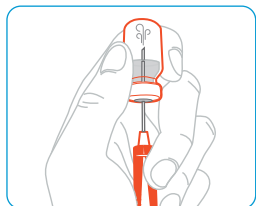
STEP E. INJECT AIR INTO VIAL



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

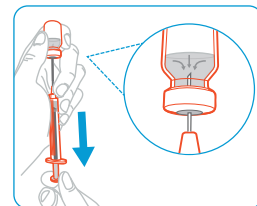


- Keep the transfer needle with filter in the vial and turn the vial upside down.



- With the needle pointing upwards, inject the air from the syringe **above the medicine**.
- Keep your finger pressed down on the syringe plunger.
- **Do not** inject air into the medicine as this could create air bubbles 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 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 with filter to inject medicine as this may cause harm such as pain and bleeding.

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



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 under Special Authority for patients who meet predefined criteria.
HEMLIBRA is not funded for people with Haemophilia A without inhibitors.**

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-00000504/NA13661/2022MAR ROC00602