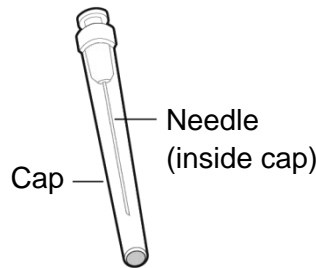


Instructions for Use
HEMLIBRA® (hem-lee-bruh)
(emicizumab-kxwh)
injection, for subcutaneous use

Transfer Needle with Filter

(For transfer of HEMLIBRA from vial to syringe)



Be sure that you read, understand, and follow this Instructions for Use before injecting HEMLIBRA. Your healthcare provider should show you or your caregiver 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 medicine strength(s) needed to give the dose prescribed by your healthcare provider.
- Your healthcare provider will determine your dose in milliliters (mL) that you will need to give based on your body weight.
- HEMLIBRA comes in four strengths. Depending on your dose, you may need to use more than one vial to give your total prescribed dose. **Do not combine HEMLIBRA vials of different concentrations in one injection** to give the prescribed dose.
- Check the expiration date on the box and vial label. **Do not** use if the expiration date has passed.
- **Only use the vial one time.** After you inject your dose, dispose of (throw away) any unused HEMLIBRA left in the vial. Do not save unused HEMLIBRA in the vial for later use.
- **Only use the syringes, transfer needles, and injection needles that your healthcare provider prescribes.**
- **Only use the syringes, transfer needles and injection needles one time.** Dispose of (throw away) any used syringes and needles in a sharps disposal container.

- If your prescribed dose is more than 2 mL, you will need to give more than one injection of HEMLIBRA.

Storing HEMLIBRA:

- Store HEMLIBRA in the refrigerator at 36°F to 46°F (2°C to 8°C). **Do not** freeze.
- Store HEMLIBRA in the original carton to protect the vials from light.
- **Do not** shake HEMLIBRA.
- Take the vial out of the refrigerator 15 minutes before use and allow it to reach room temperature before preparing an injection.
- Before giving the injection, unopened vials of HEMLIBRA may be stored out of the refrigerator and then returned to the refrigerator. HEMLIBRA should not be stored out of the refrigerator:
 - for more than a total of 7 days **or**
 - at a temperature greater than 86°F (30°C).

Keep HEMLIBRA and all medicines out of the reach of children.

Inspecting the HEMLIBRA vial and your supplies:

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

HEMLIBRA is colorless to slightly yellow in color. Do not use the vial if:

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

Included in the box:

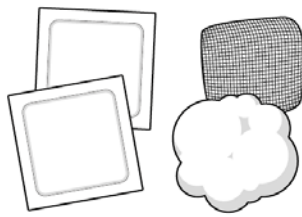


- **Vial containing HEMLIBRA**

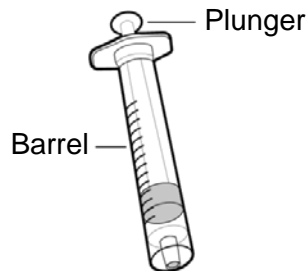


- **HEMLIBRA Instructions for Use**

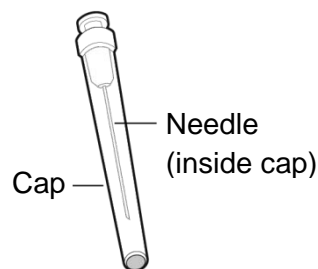
Not included in the box:



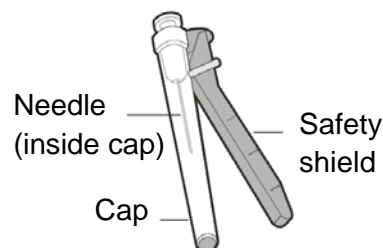
- **Alcohol wipes**
Note: If you need to use more than one vial to inject your prescribed dose, you must use a new alcohol wipe for each vial.
- **Gauze**
- **Cotton Ball**



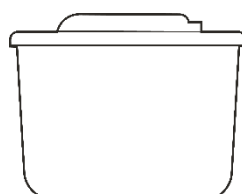
- **Syringe**
Note: For injection amount up to 1 mL, use a **1 mL syringe**. For injection amount between 1 mL and 2 mL, use a **2 mL or 3 mL syringe**.



- **18 gauge Transfer needle with 5 micrometer filter.**
Note: If you need to use more than one vial to inject your prescribed dose, you must use a new transfer needle for each vial.
Do not use the transfer needle to inject HEMLIBRA.



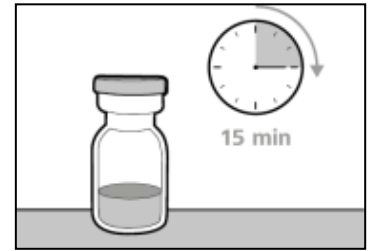
- **Injection Needle with safety shield.** You may use a 25, 26 or 27 gauge needle.
Do not use the injection needle to withdraw HEMLIBRA from vial.



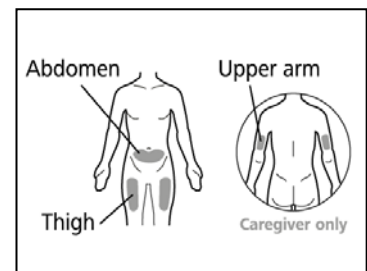
- **Sharps disposal container**

Get ready:

- Before use, allow the vial(s) to warm up to room temperature for about 15 minutes on a clean flat surface away from direct sunlight.
- Do not try to warm the vial by any other way.
- Wash your hands well with soap and water.

**Selecting and preparing an injection site:**

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



- **You can use your:**
 - Thigh (front and middle).
 - Stomach area (abdomen), except for 2 inches around the navel (belly button).
 - Outer area of the upper arm (only if a caregiver is giving the injection).
- You should use a different injection site each time you give an injection, at least 1 inch 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:

- HEMLIBRA must not be stored **in the syringe**.
- HEMLIBRA in the syringe must be injected under the skin (subcutaneous injection) immediately.
- **Dispose of (throw away) any used vial(s), needles, vial and injection needle caps, and used syringes in a sharps disposal container.**

Important information after the injection:

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

Disposing of used HEMLIBRA vial(s), needles, and syringes:

- Put your used needles and syringes in a FDA-cleared sharps disposal container right away after use. Do not dispose of (throw away) any loose needles and syringes in your household trash.
- If you do not have a FDA-cleared 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 labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.
- Do not dispose of (throw away) any used sharps disposal container in your

household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

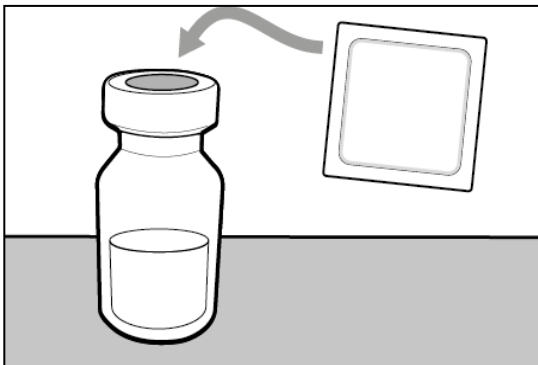
Important: Always keep the sharps disposal container out of reach of children.

1. PREPARATION

Step 1. Remove vial cap and clean top

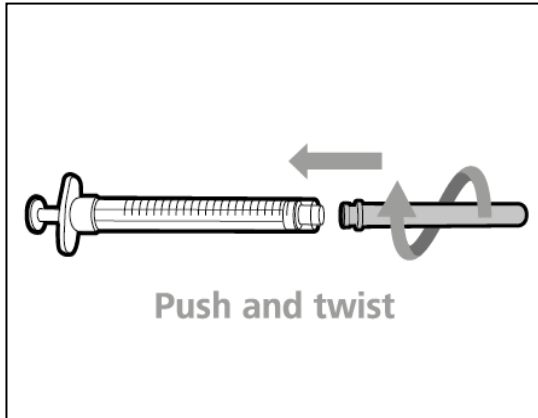


- Take the cap off the vial(s).

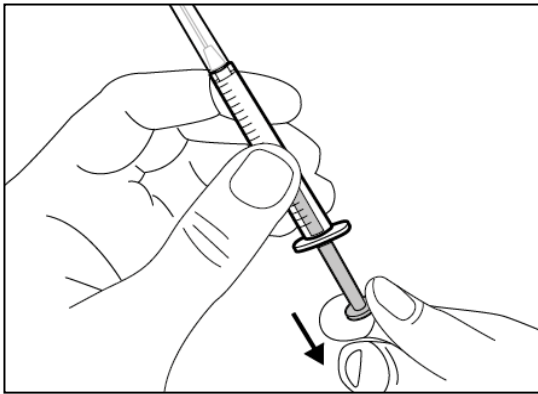


- Clean the top of the vial(s) stopper with an alcohol wipe.
- Dispose of (throw away) the vial cap(s) into the sharps disposal container.

Step 2. Attach transfer needle with filter to syringe

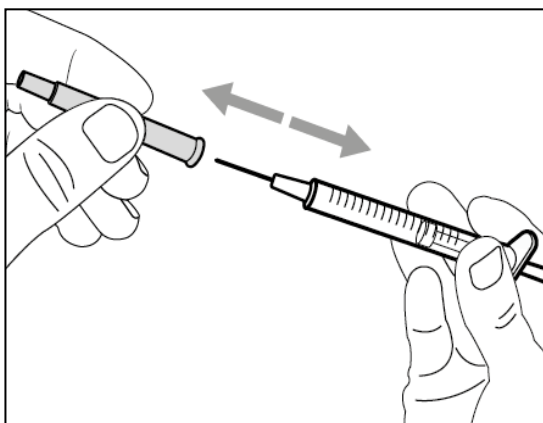


- **Push and twist the transfer needle with filter clockwise** on to the syringe until it is fully attached.



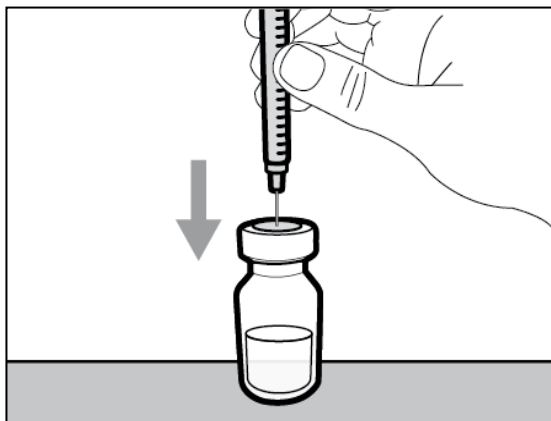
- Slowly pull back on the plunger and draw air into the syringe that is the same amount for your prescribed dose.

Step 3. Uncap transfer needle

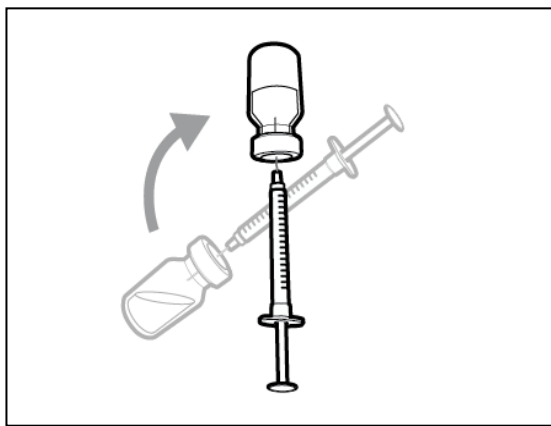


- Hold the syringe by the barrel with the transfer needle pointing up.
- Carefully pull the transfer needle cap straight off and away from your body. **Do not throw the cap away. Place the transfer needle cap down on a clean flat surface.** You will need to recap the transfer needle after transferring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

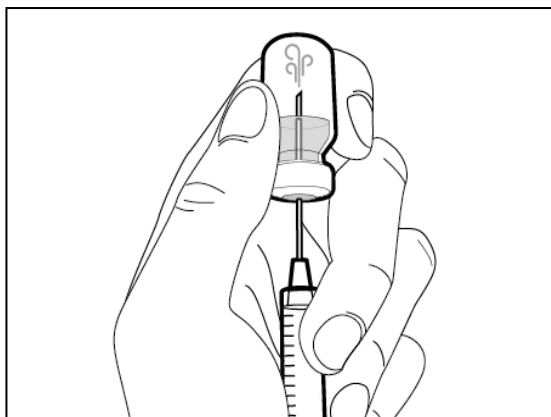
Step 4. Inject air into vial



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

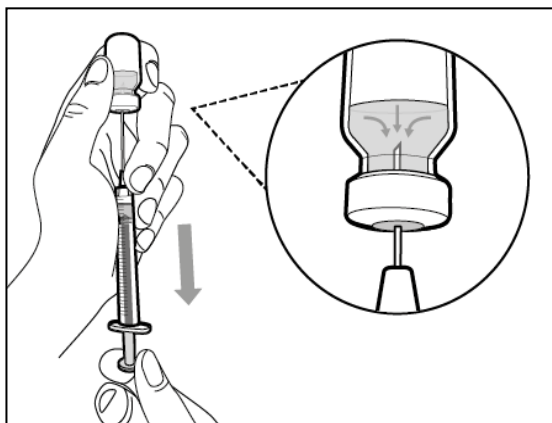


- Keep the needle in the vial and turn the vial upside down.



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

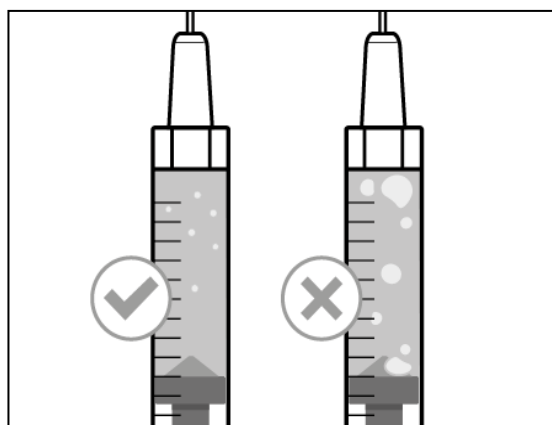
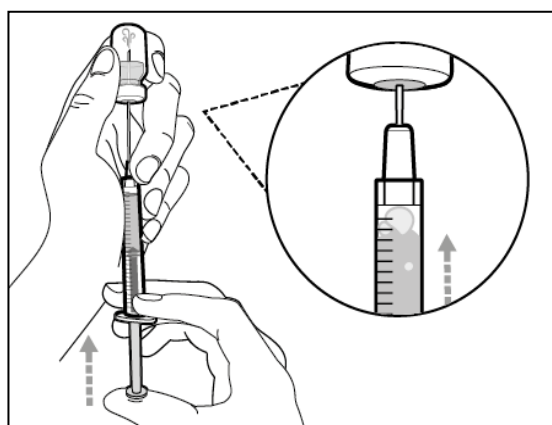
Step 5. Transfer HEMLIBRA to syringe



- Slide the tip of the needle down so that it is **within the medicine**.
- Slowly pull back the plunger to prevent air bubbles/foam. Fill the syringe with more than the amount of HEMLIBRA 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 HEMLIBRA** and go to the “**Combining Vials**” section now.

Step 6. Remove air bubbles



- Keep the needle in the vial and check the syringe for larger air bubbles. Too large an air bubble can reduce the dose you receive.
- **Remove the larger air bubbles** by gently tapping the syringe barrel with your fingers until the air bubbles rise to the top of the syringe. Move the tip of the needle **above the medicine** and slowly push the plunger up to push the air bubbles out of the syringe.
- If the amount of HEMLIBRA 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 HEMLIBRA 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.

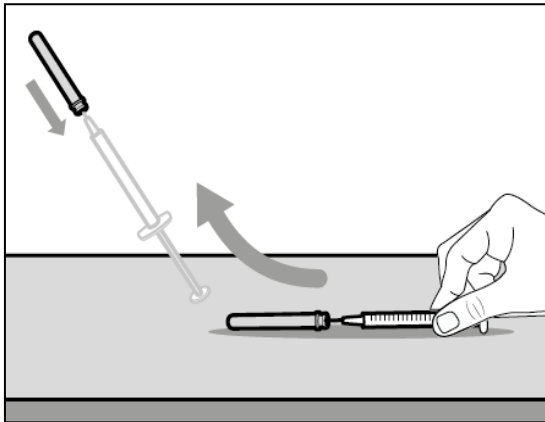
Note: Ensure you have enough HEMLIBRA in the syringe to complete your dose before moving on to the next step. If you cannot remove all of HEMLIBRA, turn the vial upright to reach the remaining amount.



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

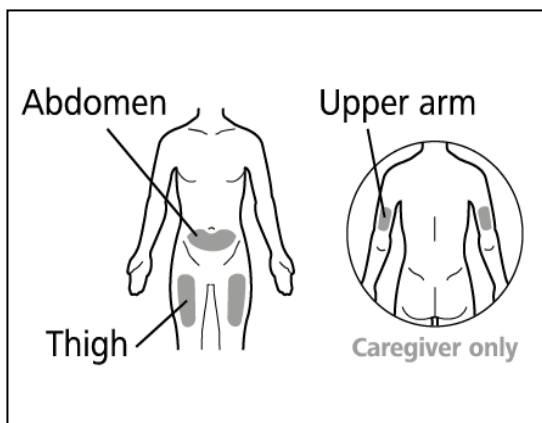
2. INJECTION

Step 7. Recap transfer needle



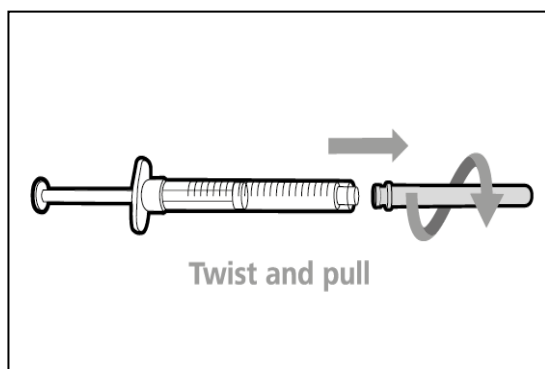
- Remove the syringe and transfer needle from the vial.
- **Using one hand, slide** the transfer needle into the cap and **scoop upwards** to cover the needle.
- Once the needle is covered, push the transfer needle cap towards the syringe to fully attach it with **one hand** to prevent accidentally sticking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

Step 8. Clean injection site



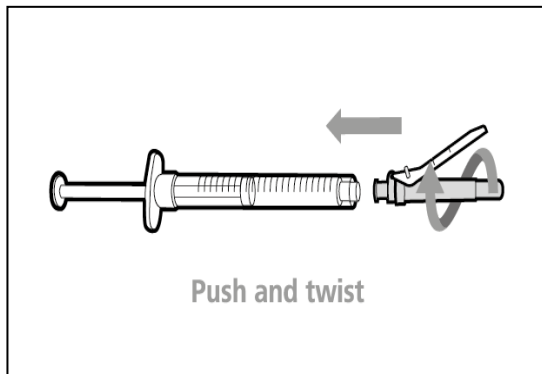
- Select and **clean** your injection site with an alcohol wipe.
- Let the skin dry for about 10 seconds. Do not touch, fan, or blow on the cleaned area before your injection.

Step 9. Remove transfer needle



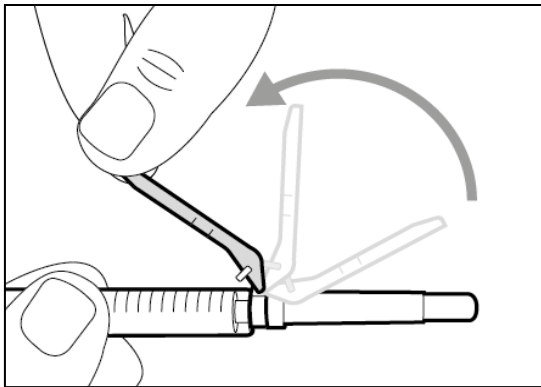
- Remove the transfer needle from the syringe by twisting counter-clockwise and gently pulling.
- Dispose of (throw away) the used transfer needle into a sharps disposal container.

Step 10. Attach injection needle to syringe



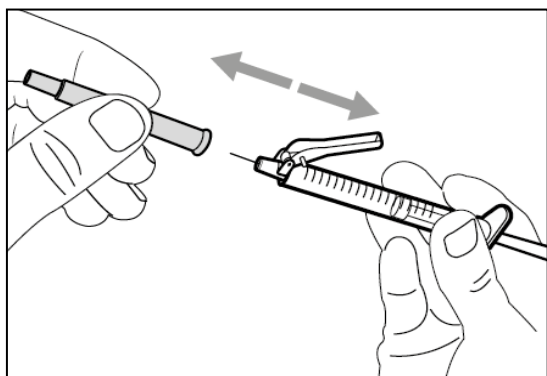
- Push and twist the injection needle clockwise on to the syringe until it is fully attached.

Step 11. Move safety shield



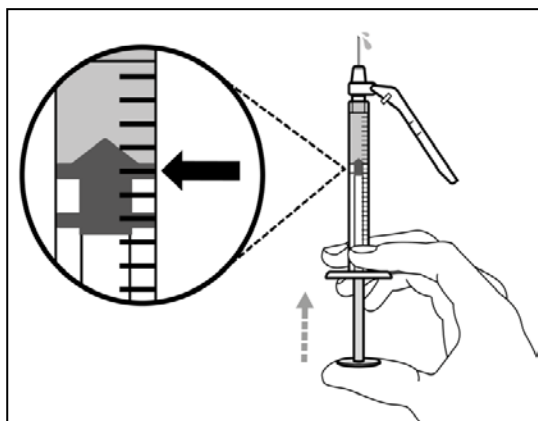
- Move the safety shield away from the needle and **towards** the syringe barrel.

Step 12. Uncap injection needle



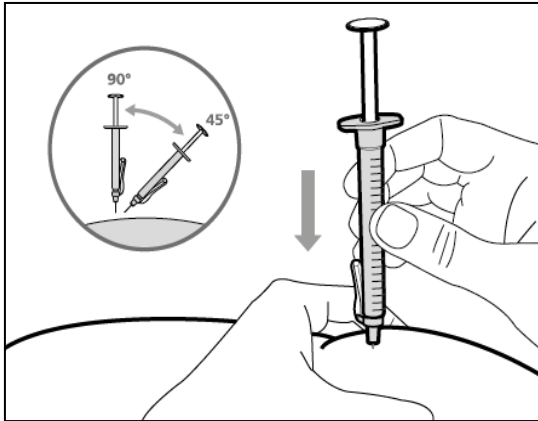
- Carefully pull the injection needle cap away from the syringe.
- Dispose of (throw away) the cap into a sharps disposal container.
- **Do not touch** the needle tip or allow it to touch any surface.
- After the injection needle cap has been removed, HEMLIBRA in the syringe must be injected right away.

Step 13. Adjust plunger to prescribed dose



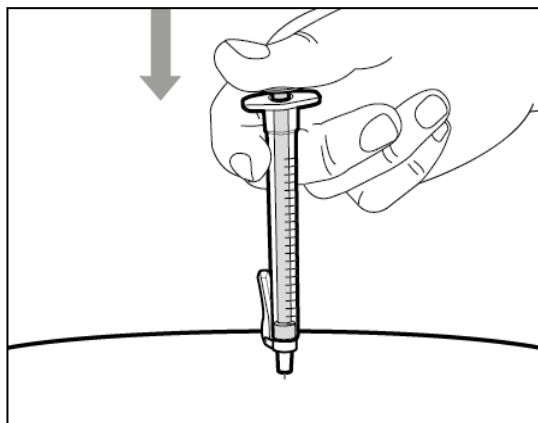
- Slowly push the plunger to your prescribed dose.
- Ensure the top rim of the plunger is in line with the mark on the syringe for your prescribed dose.

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.

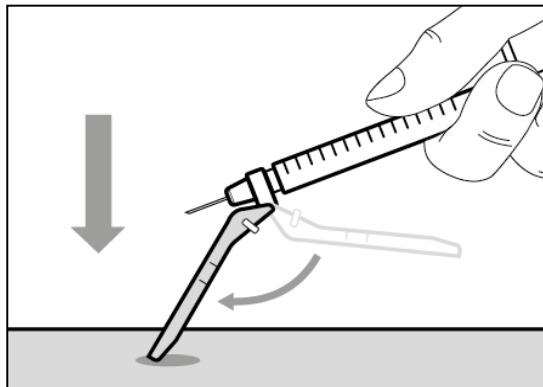
Step 15. Inject HEMLIBRA



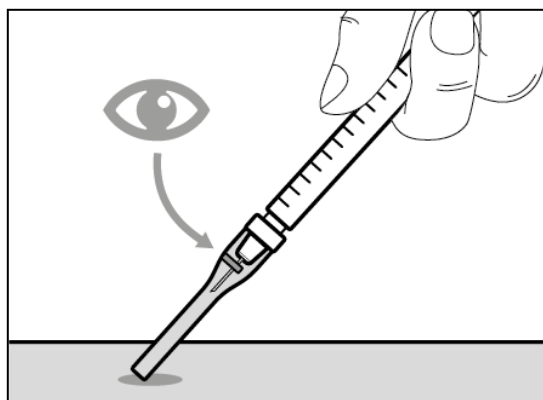
- Slowly inject all of HEMLIBRA by gently pushing the plunger all the way down.
- Remove the needle and syringe from the injection site at the same angle as inserted.

3. DISPOSAL

Step 16. Cover needle with safety shield

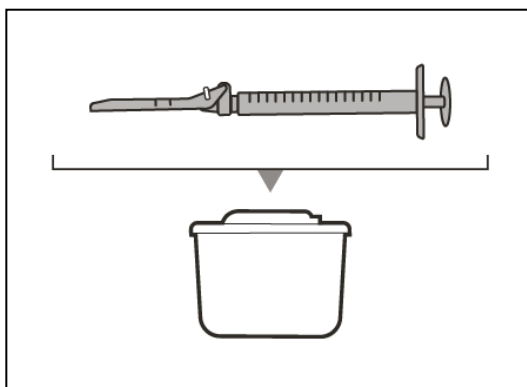


- Move the safety shield forward 90°, away from the syringe barrel.
- Holding the syringe with one hand, **press the safety shield down** against a flat surface with a firm, quick motion until you hear a “click”.



- 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** remove the injection needle from the syringe.

Step 17. Dispose of (throw away) the used HEMLIBRA vial(s), needle, and syringe

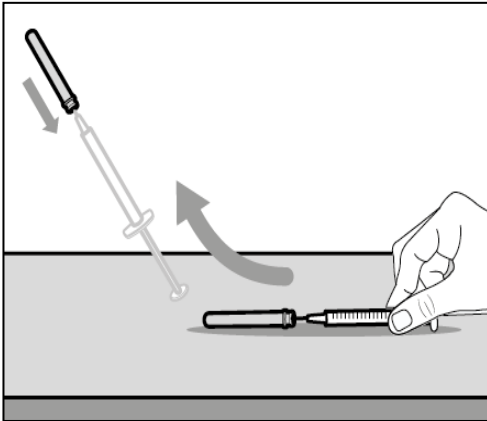


- Put your used needles and syringes in a FDA-cleared sharps disposal container right away after use. For further information, refer to the section “Disposing of used HEMLIBRA vial(s), needles, and syringes” above.
- **Do not** try to remove the used injection needle from the used syringe.
- **Do not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

Combining Vials

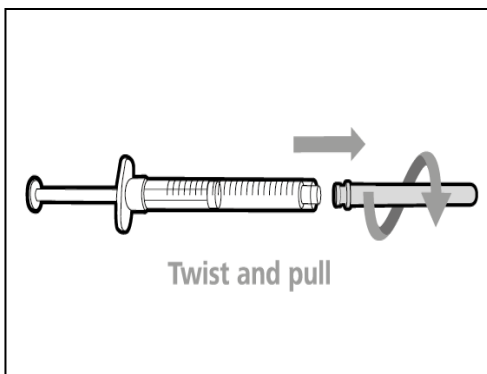
If you need to use more than one vial to get to your total prescribed dose, follow these steps after you have drawn up HEMLIBRA from the first vial:

Step A. Recap transfer needle



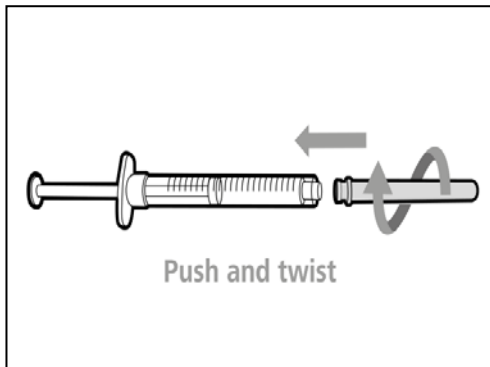
- Remove the syringe and transfer needle from the first vial.
- **Using one hand**, slide the transfer needle into the cap and **scoop upwards** to cover the needle.
- Once the needle is covered, push the transfer needle cap toward the syringe to fully attach it with **one hand** to prevent accidentally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

Step B. Remove transfer needle



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

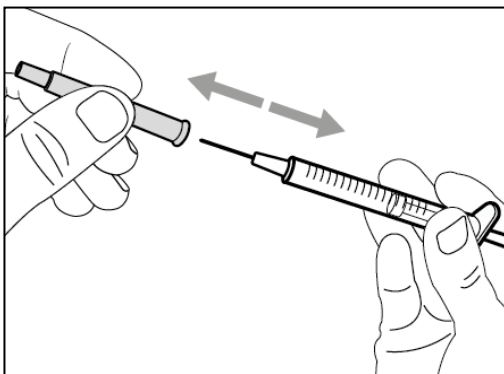
Step C. Attach a new transfer needle with filter to syringe



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

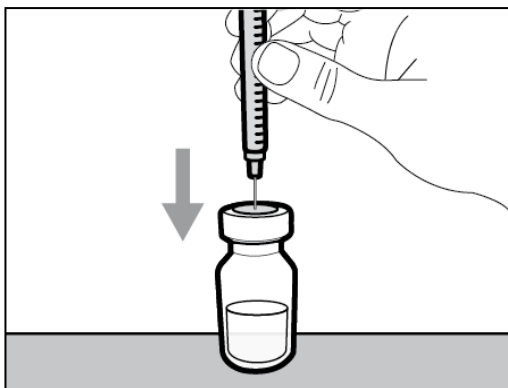
- Push and twist a **new** transfer needle clockwise on to the syringe until it is fully attached.
- Slowly pull back the plunger and draw some air into the syringe.

Step D. Uncap transfer needle

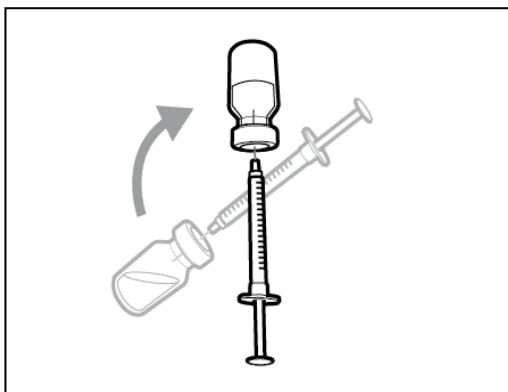


- Hold the syringe by the barrel with the transfer needle cap pointing up.
- Carefully pull the transfer needle cap straight off and away from your body. **Do not throw the cap away.** You will need to recap the transfer needle after drawing up the medicine.
- **Do not touch** the needle tip.

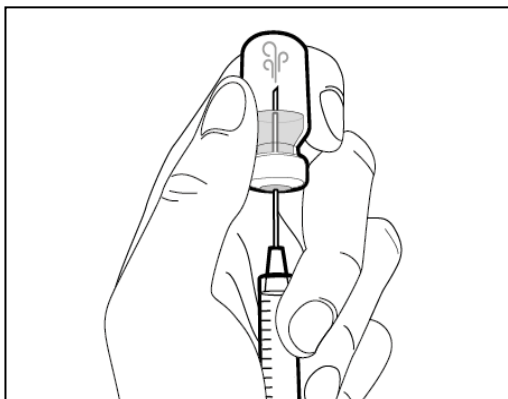
Step E. Inject air into vial



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

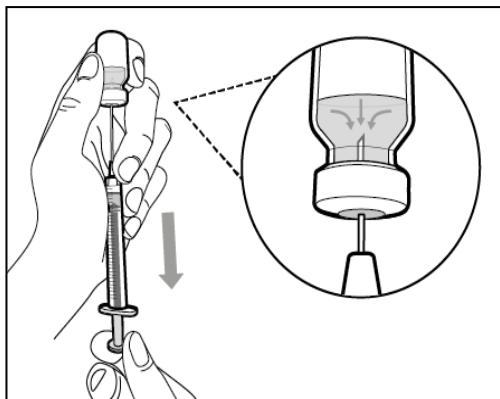


- Keep the transfer needle in the vial and turn the vial upside down.



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

Step F. Transfer HEMLIBRA to syringe



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

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

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

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

For more information, go to www.HEMLIBRA.com or call 1-866-HEMLIBRA.

HEMLIBRA® [emicizumab-kxwh]

Manufactured by:

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A Member of the Roche Group

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South San Francisco, CA 94080-4990

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