

Instructions for Use
SEMGLEE® (Sehm-GLEE)
(insulin glargine-yfgn) injection for subcutaneous use
10 mL Vial (100 Units/mL, U-100)

Read the Instructions for Use before you start taking SEMGLEE and each time you get a new SEMGLEE vial. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Do not share your SEMGLEE syringes with other people even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.

Supplies needed to give your injection:

- a SEMGLEE 10 mL vial
- a U-100 insulin syringe and needle
- 2 alcohol swabs
- 1 sharps container for throwing away used needles and syringes. See **“Disposing of used needles and syringes”** at the end of these instructions.

Preparing your SEMGLEE dose:

- Wash your hands with soap and water or with alcohol.
- Check the SEMGLEE label to make sure you are taking the right type of insulin. This is especially important if you use more than 1 type of insulin.
- Check the insulin to make sure it is clear and colorless. **Do not** use SEMGLEE if it is colored or cloudy, or if you see particles in the solution.
- **Do not** use SEMGLEE after the expiration date stamped on the label or 28 days after you first use it.
- **Always use a syringe that is marked for U-100 insulin.** If you use a syringe other than a U-100 insulin syringe, you may get the wrong dose of insulin.
- **Always use a new syringe or needle for each injection. Do not reuse or share your syringes or needles with other people. You may give other people a serious infection or get a serious infection from them.**

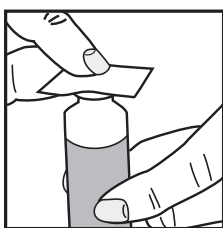
Step 1:

If you are using a new vial, remove the protective cap. **Do not** remove the rubber stopper.



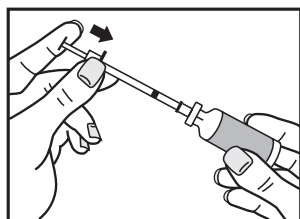
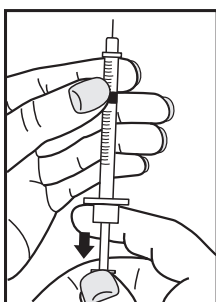
Step 2:

Wipe the top of the vial with an alcohol swab. You do not have to shake the vial of SEMGLEE before use.



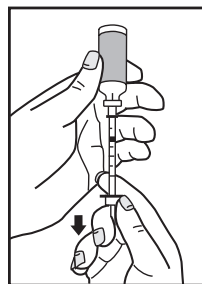
Step 3:

Draw air into the syringe equal to your insulin dose. Put the needle through the rubber top of the vial and push the plunger to inject the air into the vial.



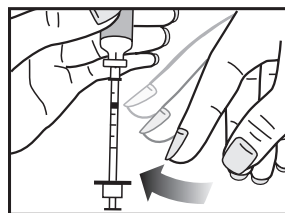
Step 4:

Leave the syringe in the vial and turn both upside down. Hold the syringe and vial firmly in one hand. Make sure the tip of the needle is in the insulin. With your free hand, pull the plunger to withdraw the correct dose into the syringe.



Step 5:

Before you take the needle out of the vial, check the syringe for air bubbles. If bubbles are in the syringe, hold the syringe straight up and tap the side of the syringe until the bubbles float to the top. Push the bubbles out with the plunger and draw insulin back in until you have the correct dose.



Step 6:

Remove the needle from the vial. Do not let the needle touch anything. You are now ready to inject.

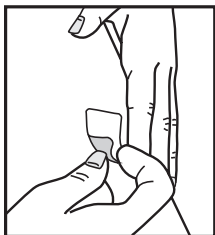
Giving your SEMGLEE injection:

- Inject your insulin exactly as your healthcare provider has shown you.
- Inject your insulin under the skin (subcutaneously) of your upper legs (thighs), upper arms, or stomach area (abdomen).

- **Change (rotate) your injection sites within the area you choose for each dose** to reduce your risk of getting lipodystrophy (pits in the skin or thickened skin) and localized cutaneous amyloidosis (skin with lumps) at the injection sites.
- Do not inject where the skin has pits, is thickened, or has lumps.
- Do not inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.

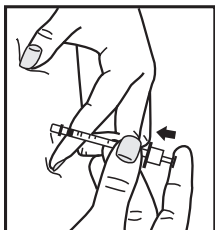
Step 7:

Choosing your injection site: SEMGLEE is injected under the skin (subcutaneously) of your upper arm, thigh, or stomach area (abdomen). Wipe the skin with an alcohol swab to clean the injection site. Let the injection site dry before you inject your dose.



Step 8:

- Pinch the skin.
- Insert the needle in the way your healthcare provider showed you.
- Release the skin.
- Slowly push in the plunger of the syringe all the way, making sure you have injected all the insulin.
- Leave the needle in the skin for about **10** seconds.



Step 9:

- Pull the needle straight out of your skin.
- Gently press the injection site for several seconds. **Do not** rub the area.
- **Do not** recap the used needle. Recapping the needle can lead to a needle stick injury.

Disposing of used needles and syringes:

- Put your used needles and syringes in a FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) loose needles and syringes in your household trash.
- If you do not have a FDA-cleared sharps container, you may use a household container that is:
 - o made of a heavy-duty plastic,
 - o can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - o upright and stable during use,
 - o leak resistant, and
 - o 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 your used sharps disposal container in your household trash unless your community guidelines permit this. **Do not** recycle your used sharps disposal container.

How should I store SEMGLEE?

- Store unused SEMGLEE vials in the refrigerator at 36° to 46°F (2° to 8°C).
- Store in-use (opened) SEMGLEE vials in a refrigerator or at room temperature up to 86°F (30°C).
- **Do not** freeze SEMGLEE.
- Keep SEMGLEE out of direct heat and light.
- If a vial has been frozen or overheated, throw it away.
- The SEMGLEE vials you are using should be thrown away after **28** days, even if it still has insulin left in it.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Approved: 7/2021

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 Morgantown, WV 26505 U.S.A.
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