

INSTRUCTIONS FOR USE

Semglee™ (Sehm-GLEE)

(insulin glargine injection)

For Single Patient Use Only

100 units/mL (U-100)

1 Prefilled pen with 3 mL cartridge



Read this Instructions for Use carefully before using SEMGLEE single-patient-use prefilled pen and each time you get another pen. 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. If you are unable to read or follow all of the instructions on your own, ask for help from someone trained to use this pen.

Your healthcare provider should show you or a caregiver how to use SEMGLEE the right way before you use it for the first time.

If you do not follow these instructions each time you use the pen, you may either get too much or too little insulin. This may affect your blood sugar level.

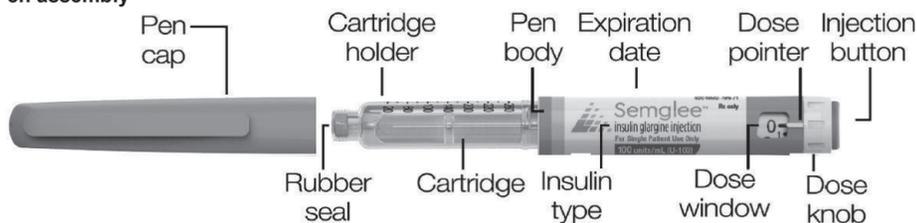
SEMGLEE is a disposable single-patient-use prefilled pen injector that contains a total of 300 units of insulin glargine. Each pen contains more than one dose of medicine. You can select doses from 1 to 80 units in steps of 1 unit. If your prescribed dose is more than 80 units, you will need to give yourself more than 1 injection.

Do not share your SEMGLEE prefilled pen 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.

People who are blind or have vision problems should not use SEMGLEE prefilled pen without help from a person trained to use SEMGLEE prefilled pen.

Before you use the pen for the first time check that the SEMGLEE disposable prefilled pen injector carton is sealed and that the sticker sealing the carton is not broken. After opening the carton look at the pen to make sure that it looks new and is not broken.

Pen assembly



BD Ultra-Fine needles are compatible with SEMGLEE.

Needles are sold separately.

Required Supplies

- SEMGLEE single-patient-use prefilled pen
- Needle compatible with this pen
- Alcohol wipes
- A sharps container to throw away used needles. See “Step 8 Needle disposal” at the end of this Instructions for Use.

Storage

Unused Pens

- Before using the pen, store the cartons containing the pen in the refrigerator between 36°F to 46°F (2°C to 8°C) until the expiration date. If your unused pen is stored at room temperature up to 86°F (30°C), it should be thrown away after 28 days.
- **Do not** freeze the pen.

In-use Pen

- When using a new pen that has been stored in the refrigerator, take the pen out of the refrigerator. Rest it on a flat surface and wait for it to reach room temperature.
- While using the pen, store it at room temperature up to 86°F (30°C). **Do not** put the pen back in the refrigerator after using it.
- Always store the pen with the pen cap on to prevent contamination. **Do not** leave the needle attached to the pen during storage or re-use needles. You should safely throw away any used needles. See “Step 8 Needle disposal” at the end of this Instructions for Use.
- The pen that you are using should be thrown away 28 days after removing it from the refrigerator, even if the pen has insulin left in it.

Keep your pen and needles out of sight and reach of children.

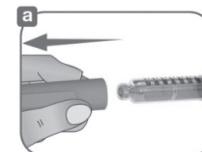
Always use a new sterile needle for each injection as this helps stop blocked needles and prevents infections.

Each time you use the pen

- Wash your hands with soap and water before using your pen.
- Check the pen label to make sure that it is the correct type of insulin. The pen has a purple and white label and a purple injection button.
- Check the expiration date on the pen label. **Do not** use the pen after the expiration date.
- Check that the medicine in the pen cartridge looks clear and colorless. **Do not** use the pen if the medicine in the cartridge looks cloudy, colored or if you can see particles.
- Always use a new sterile disposable needle for each injection.
- Use an injection site that your healthcare provider has shown you.

Step 1. Prepare your pen

- A** Inspect the pen. Check the purple and white label on the pen to make sure:
- It is the correct insulin type.
 - The expiration date has not passed.
- B** Hold the pen body with 1 hand. With the other hand pull off the pen cap. Put the pen cap off to the side to be used later (See Figure a).
- Check the insulin through the cartridge holder to make sure:
- C**
- The insulin looks clear and colorless.
 - There are no cracks, breaks or leaks around the cartridge holder.
- D** Wipe the rubber seal (at the front of the cartridge) with a new alcohol wipe (See Figure b).



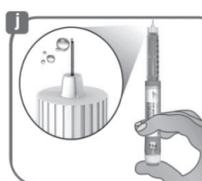
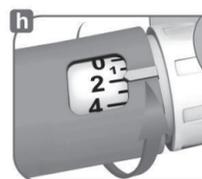
Step 2. Attach a new needle

- A** Take a new sterile disposable needle and peel off the protective tab (See Figure c). **Do not** use the needle if the protective tab is damaged or missing, as the needle may not be sterile.
- B** While holding the pen body facing upwards, attach the outer cap straight on to the cartridge holder as shown. **Do not** attach the outer cap sideways as this may cause the needle to bend or become damaged (See Figure d).
- C** Turn the outer cap in a clockwise (right) direction until it feels tightly fixed on the pen (See Figure e).
- D** Carefully pull off the outer cap and put it off to the side (See Figure f). **Do not** throw it away. You will need the outer cap later.
- E** Carefully pull off the inner cap and throw it away in the sharps container (See Figure g).



Step 3. Prime your pen needle

- A** Always prime a new pen needle before each injection.
- B** Turn the white dose knob to 2 dose units (See Figure h). You will hear a “click” for each unit turned.
- If you accidentally turn past 2 units, turn back the dose knob in the opposite direction to the correct number of units.
- C** Hold the pen body facing upwards with 1 hand.
- D** Tap the cartridge gently with your finger to help any large air bubbles to move to the top of the cartridge (See Figure i). Small bubbles may still be visible. This is normal.
- E** With the pen needle facing upwards, press the injection button until it stops moving and the dose window shows “0”.
- F** Repeat steps 3B through 3E up to 4 times until you see drops of insulin at the tip of the needle. Priming is complete when you can see drops of insulin (See Figure j).



If you do not see any insulin at the needle tip after trying to prime the needle 4 times, the needle may be clogged. If this occurs:

- Go to Step 7 for instructions on safely removing the needle.
- Restart the process at step 2A to attach and prime a new needle.

Step 4. Select your dose

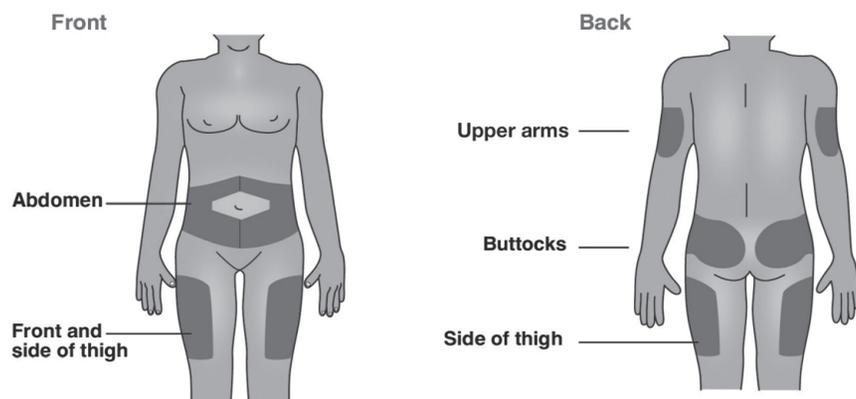
- A** Check that the dose window shows "0".
- B** Turn the white dose knob until the yellow dose pointer lines up with your required dose.

- The pen dials 1 unit at a time.
- The white dose knob clicks and becomes longer as you turn it.
- **Do not** push the purple injection button while you are turning the white dose knob.
- **Do not** dial your dose by counting the clicks because you may dial the wrong dose.
- The **even** numbers are printed on the dial (See Figure k). The **odd** numbers are shown as lines in between the even numbers (See Figure l).
- You can correct the dose by turning the dose knob in either direction until the correct dose lines up with the yellow dose pointer.
- **Do not** force the white dose knob to turn beyond 80 units. If you need a dose greater than 80 units you should give it as two or more injections.
- The pen will not let you dial a dose more than the number of units left in the pen. If your dose is more than the number of units left in the pen you can either:
 - Inject the amount left in your pen and use a new pen to give the rest of your dose
 - or
 - Get a new pen and inject the full dose.

Do not push the purple injection button when turning the white dose knob.

Step 5. Select and clean the injection site

- A** Select the injection site as explained to you by your healthcare provider. SEMGLEE is injected under the skin (subcutaneously) of your stomach area (abdomen), thigh, buttocks or upper arms. You should change (rotate) your injection site for each injection. Clean with a new alcohol wipe and let your skin dry before you inject your dose.



Inject your insulin exactly as your healthcare provider has shown you.

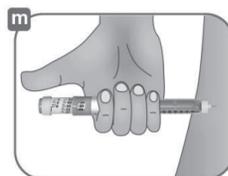
Change (rotate) your injection sites within the area you choose for each dose to reduce your risk of getting pits in the skin or thickened skin (lipodystrophy) and skin with lumps (localized cutaneous amyloidosis) at the injection sites.

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 6. Inject your dose

- A** Some injection sites may need to be pinched during your injection. Ask your healthcare provider if you are not sure if your skin needs to be pinched during the injection. If instructed by your healthcare provider you can pinch the cleaned skin between your fingers.
- B** Push the needle straight into the skin as shown by your healthcare provider (See Figure m). **Do not** inject with the needle at an angle.



- C** Press the purple injection button all the way in (See Figure n). The white dose knob will turn and you will hear "clicks" as you press down.



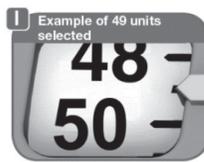
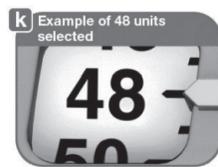
- D** After the dose window shows "0", continue to hold the purple injection button down and slowly count to 10 to make sure that the full dose of insulin is injected. If you do not keep the injection button pressed down for 10 seconds after "0" is displayed you may get the wrong dose of medicine (See Figure o).



Do not push the injection button sideways or block the white dose knob with your fingers as this will stop you from injecting the medicine.

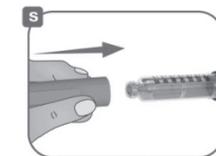
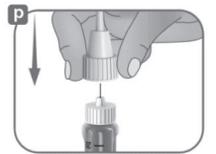
Pull the needle out of your skin.

A drop of insulin at the needle tip is normal. It will not affect your dose.



Step 7. After your injection

- A** Take the outer cap that you had saved in step 2D, hold it at the widest part and carefully cover the needle without touching it (See Figure p).
- B** Squeeze the wide part of the outer cap and unscrew the needle in a counter-clockwise (left) direction (See Figure q). Keep twisting the needle until it comes off the pen. It may take several twists to release the needle.
- C** Put the needle in a sharps disposal container (See Step 8 Needle disposal at the end of this Instructions for Use) (See Figure r).
- D** Replace the pen cap over the cartridge (See Figure s).
- E** If there is still medicine left in your pen, store the pen at room temperature (up to 86°F or 30°C). **Do not** store the pen with a used needle attached.



Step 8. Needle disposal

Put your used needle in an FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) loose needles in your household trash.

If you do not have an FDA-cleared sharps 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, and
- Properly labeled to warn of hazardous waste inside the container.

When your sharps disposable container is almost full you will need to follow your community guidelines for the right way to dispose of your sharps 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 website at: www.fda.gov/safesharpsdisposal

Do not dispose of a used sharps disposal container in your household trash unless guidelines permit this. **Do not** recycle your used sharps disposal container.

Pen care

- Always carry an extra insulin pen in case your pen gets lost or damaged.
- Always use a new sterile disposable needle for each injection.
- Protect SEMGLEE from direct heat and light.
- The used pen may be discarded in your household trash after you have removed the needle.
- You can clean the outside of your pen by wiping it with a damp cloth.
- Avoid dropping your pen as this can cause the cartridge to break, or can damage the pen.
- **Do not** share your pen with other people, even if the needle has been changed. You may give other people serious infection or get a serious infection from them.
- **Do not** soak or wash your pen. **Do not** use alcohol, hydrogen peroxide, bleach, or any other liquids to clean your pen. **Do not** apply lubricants such as oil. This could damage the pen.
- **Do not** try to fix an unusable or damaged pen. Remove the needle as shown in Step 7, safely throw it away in a sharps container as shown in Step 8 and return the pen to the manufacturer letting them know of the problem. Use a new pen instead.

This Instructions for Use has been approved by the Food and Drug Administration. Approved: 6/2020

BD Ultra-Fine™ is a trademark of Becton, Dickinson, and Company. SEMGLEE™ is a trademark of Mylan Pharmaceuticals, Inc.



Manufactured for:
Mylan Specialty L.P.
Morgantown, WV 26505 U.S.A.

Manufactured by: **Biocon Sdn. Bhd.**, Malaysia

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