

## INSTRUCTIONS FOR USE

### SEMGLEE® Single-Patient-Use Prefilled Pen (insulin glargine-yfgn) injection

Your healthcare professional has decided that SEMGLEE is right for you. Talk with your healthcare professional about proper injection technique before using SEMGLEE.

Read these instructions carefully before using your SEMGLEE. If you are not able to follow all the instructions completely on your own, use SEMGLEE only if you have help from a person who is able to follow the instructions.

**Do not share your SEMGLEE 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.**

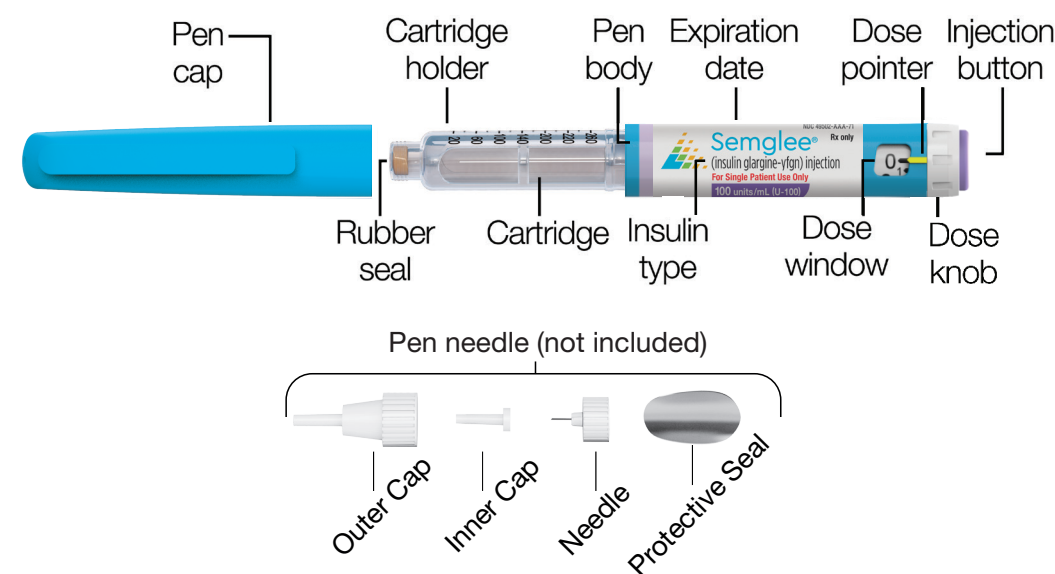
**People who are blind or have vision problems should not use SEMGLEE single-patient-use prefilled pen without help from a person trained to use SEMGLEE single-patient-use prefilled pen.**

**Follow these instructions completely each time you use SEMGLEE to ensure that you get an accurate dose. If you do not follow these instructions you may get too much or too little insulin, which may affect your blood glucose.**

SEMGLEE is a disposable pen for the injection of insulin. Each SEMGLEE contains in total 300 units of insulin. You can set doses from 1 to 80 units in steps of 1 unit. The pen plunger moves with each dose. The plunger will only move to the end of the cartridge when 300 units of insulin have been given.

Keep this leaflet for future reference.

If you have any questions about SEMGLEE or about diabetes, ask your healthcare professional, or call Mylan at 1-877-446-3679 (1-877-4-INFO-RX).



#### Important information for use of SEMGLEE:

- **Do not share your SEMGLEE 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.
- Do not re-use needles. Always attach a new needle before each use.
- BD® Ultra-Fine needles are compatible with SEMGLEE. These are sold separately and are manufactured by BD. Contact your healthcare professional for further information.
- Always perform the safety test before each injection.
- Do not select a dose or press the injection button without a needle attached.
- If your injection is given by another person, special caution must be taken by this person to avoid accidental needle injury and transmission of infection.
- Never use SEMGLEE if it is damaged or if you are not sure that it is working properly.
- Always have a spare SEMGLEE in case your SEMGLEE is lost or damaged.
- Change (rotate) your injection sites within the area you choose for each dose (see “Places to inject”).

#### Places to inject

- Inject your insulin exactly as your healthcare professional 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 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.

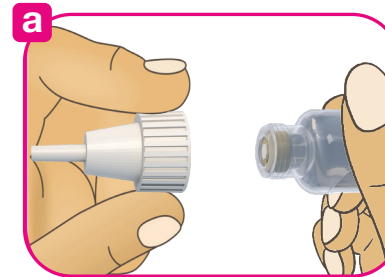
#### Step 1. Check the insulin

- Check the label on your SEMGLEE to make sure you have the correct insulin. SEMGLEE is blue with a purple injection button.
- Take off the pen cap.
- Check the appearance of your insulin. SEMGLEE is a clear insulin. Do not use this SEMGLEE if the insulin is cloudy, colored or has particles.

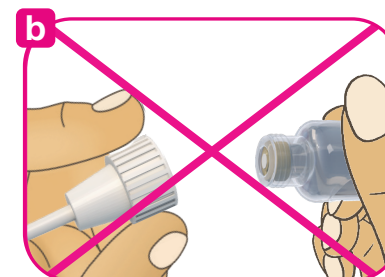
#### Step 2. Attach the needle

Do not re-use needles. Always use a new sterile needle for each injection. This helps prevent contamination and potential needle blocks.

- Wipe the rubber seal with alcohol.
- Remove the protective seal from a new needle.
- Line up the needle with the pen, and keep it straight as you screw it on (See Figure a).



- If the needle is not kept straight while you attach it, it can damage the rubber seal and cause leakage, or break the needle (See Figure b).



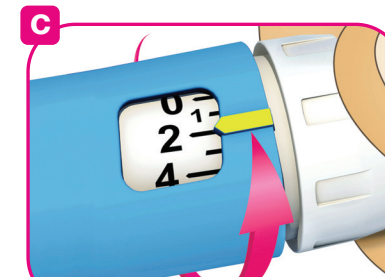
#### Step 3. Perform a Safety test

**Always perform the safety test before each injection.**

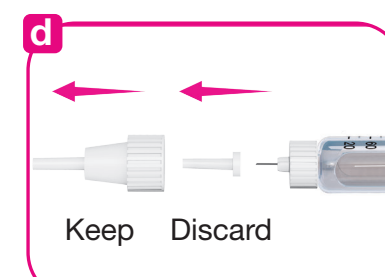
Performing the safety test ensures that you get an accurate dose by:

- ensuring that pen and needle work properly
- removing air bubbles

- Select a dose of 2 units by turning the white dose knob (See Figure c).



- Take off the outer needle cap and keep it to remove the used needle after injection. Take off the inner needle cap and discard it (See Figure d).



- Hold the pen with the needle pointing upwards.
- Tap the cartridge so that any air bubbles rise up towards the needle.
- Press the purple injection button all the way in. Check if insulin comes out of the needle tip (See Figure e).



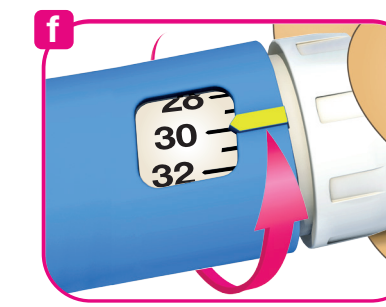
You may have to perform the safety test several times before insulin is seen.

- If no insulin comes out, check for air bubbles and repeat the safety test two more times to remove them.
- If still no insulin comes out, the needle may be blocked. Change the needle and try again.
- If no insulin comes out after changing the needle, your SEMGLEE may be damaged. Do not use this SEMGLEE.

#### Step 4. Select the dose

You can set the dose in steps of 1 unit, from a minimum of 1 unit to a maximum of 80 units. If you need a dose greater than 80 units, you should give it as two or more injections.

- Check that the dose window shows “0” following the safety test.
- Select your required dose (in the **example** below, the selected dose is 30 units, see Figure f). If you turn past your dose, you can turn back down.

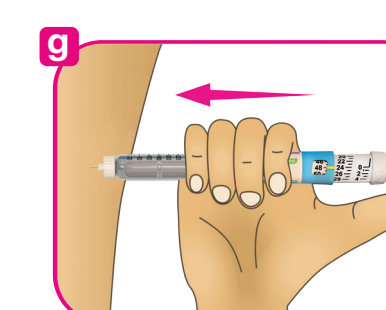


- Do not push the purple injection button while turning, as insulin will come out.
- You cannot turn the white dose knob past the number of units left in the pen. Do not force the dosage selector to turn. In this case, either you can inject what is remaining in the pen and complete your dose with a new SEMGLEE or use a new SEMGLEE for your full dose.

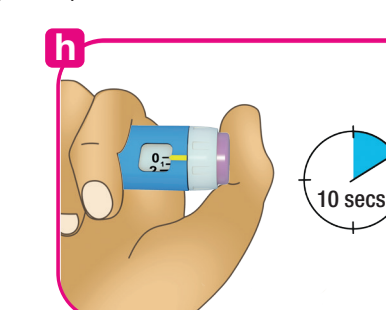
#### Step 5. Inject the dose

- Use the injection method as instructed by your healthcare professional.

- Insert the needle into the skin (See Figure g).



- Deliver the dose by pressing the purple injection button in all the way. The number in the dose window will return to “0” as you inject. The white dose knob will turn, and you will hear “clicks” as you press down (See Figure h).



- Keep the purple injection button pressed all the way in. **Slowly count to 10 before you withdraw the needle from the skin.** This ensures that the full dose will be delivered.

#### Step 6. Remove and discard the needle

Always remove the needle after each injection and store SEMGLEE without a needle attached. This helps prevent:

- Contamination and/or infection
- Entry of air into the insulin cartridge and leakage of insulin, which can cause inaccurate dosing.

- Put the outer needle cap back on the needle, and use it to unscrew the needle from the pen. To reduce the risk of accidental needle injury, never replace the inner needle cap.

- If your injection is given by another person, special caution must be taken by this person when removing and disposing the needle. Follow recommended safety measures for removal and disposal of needles (e.g., a one-handed capping technique) in order to reduce the risk of accidental needle injury and transmission of infectious diseases.

- Dispose of the needle safely. Used needles should be placed in sharps containers (such as red biohazard containers), hard plastic containers (such as detergent bottles), or metal containers (such as an empty coffee can). Such containers should be sealed and disposed of properly. If you are giving an injection to another person, you should remove the needle in an approved manner to avoid needle-stick injuries.

- Always put the pen cap back on the pen, then store the pen until your next injection.

#### Storage Instructions

Please check the leaflet for the insulin for complete instructions on how to store SEMGLEE.

If your SEMGLEE is in cool storage, take it out 1 to 2 hours before you inject to allow it to warm up. Cold insulin is more painful to inject.

Keep SEMGLEE out of the reach and sight of children.

Keep your SEMGLEE in cool storage at 36° to 46°F (2° to 8°C) until first use. **Do not** allow it to freeze. **Do not** put it next to the freezer compartment of your refrigerator or next to a freezer pack.

Once you take your SEMGLEE out of cool storage, for use or as a spare, you can use it for up to 28 days. During this time it can be safely kept at room temperature up to 86°F (30°C). Do not use it after this time. SEMGLEE in use must not be stored in a refrigerator.

Do not use SEMGLEE after the expiration date printed on the label of the pen or on the carton.

Protect SEMGLEE from light.

Discard your used SEMGLEE as required by your local authorities.

#### Maintenance

Protect your SEMGLEE from dust and dirt.

You can clean the outside of your SEMGLEE by wiping it with a damp cloth.

Do not soak, wash, or lubricate the pen as this may damage it.

Your SEMGLEE is designed to work accurately and safely. It should be handled with care. Avoid situations where SEMGLEE might be damaged. If you are concerned that your SEMGLEE may be damaged, use a new one.



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

Approved: 7/2021

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