



1 Pre-filled pen with 3 mL cartridge



INSTRUCTIONS FOR USE

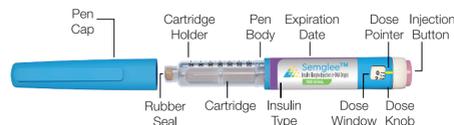
Read these **Instructions for Use** carefully before using Semglee pre-filled pen and each time you get another pen. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment. If you are unable to read or follow all of the instructions on your own, ask for help from someone trained to use this pen. **This pen is not recommended for use by the blind or visually impaired without the help of someone trained to use the pen.**

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 pre-filled disposable pen injector containing 300 units of insulin glargine in 3 mL of solution (100 units/mL). You can inject 1 to 80 units in a single injection.

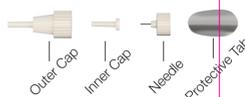
Do not share your Semglee pre-filled pen with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.

Pen assembly:



Needles to be obtained separately:

- Needles compatible with this pen:
- Novofine 32G, 6 mm
- Terumo Nanopass 34G, 4 mm
- BD Ultra-Fine 31G, 5 mm
- BD Ultra-Fine 32G, 4 mm



Required supplies:

- Make sure you have the following items before taking your dose:
- Semglee pen
- Sterile disposable hypodermic needle compatible with this pen
- 2 alcohol wipes
- Sharps disposal container

Storage

Before first using the pen, store the cartons containing the pen in the refrigerator (2°C-8°C).

Do not freeze the pen.

After you take a pen out of the refrigerator, rest it on a flat surface and wait for it to reach room temperature between 15°C to 30°C before you use it.

After first use of the pen, store it at room temperature up to 30°C. Do not put the pen back in the refrigerator after using it.

Always store the pen with the cap on, to prevent contamination.

The pen that you are using should be thrown away after 4 weeks of first use, even if it still has insulin left in it. See Step 8 for instructions on disposal.

Do not leave the needle attached to the pen during storage or reuse needles.

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 you are taking 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 colourless. **Do not** use the pen if the medicine in the cartridge looks cloudy, coloured 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.

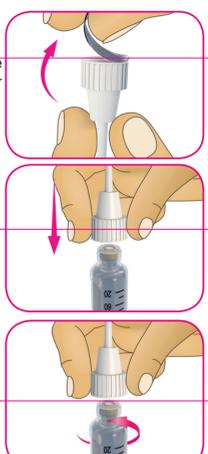
Step 1. Prepare your pen

- 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 one hand. With the other hand pull off the pen cap. Put the pen cap aside to be used later.
- C** Check the insulin through the cartridge holder to make sure:
 - The insulin looks clear and colourless.
 - 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.

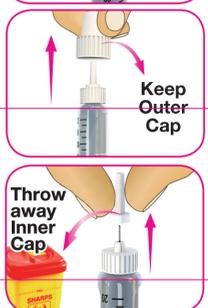


Step 2. Attach a new needle

- A** Take a new sterile disposable needle and peel off the protective seal. **Do not** use the needle if the protective seal is damaged or missing as the needle may not be sterile.
- B** While holding the pen body facing upwards, attach the outer needle cap straight on to the cartridge holder as shown. Trying to attach the outer needle cap sideways may bend or damage the needle.
- C** Turn the outer needle cap in a clockwise (right) direction until it feels tightly fixed on the pen.

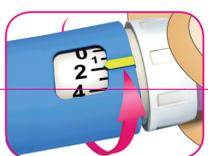


- D** Carefully pull off the outer needle cap and put it aside. **Do not** throw it away. You will need the outer needle cap later.
- E** Carefully pull off the inner needle cap and throw it away.



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. 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.



Step 3. Prime your pen needle ...Continued

- C** Hold the pen body facing upwards with one hand.
 - D** Tap the cartridge gently with your finger to help any large air bubbles to move to the top of the cartridge. Small bubbles may still be visible. This is normal.
 - E** With the pen upright, press the injection button in until it stops moving and the dose window shows "0".
 - F** Repeat steps 3B through 3E up to three more times until you see drops of insulin at the tip of the needle. Priming is complete when you can see drops of insulin.
- If you do not see any insulin at the needle tip after 4 priming attempts 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.



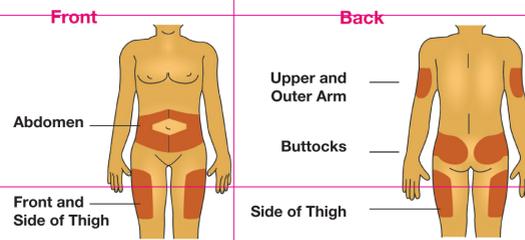
Step 4. Select your dose

- 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.
- As you turn the white dose knob to set your dose, it will extend out and you will hear a "click" at each unit dialled. The dose can be corrected by turning the dose knob in either direction until the correct dose lines up with the yellow dose pointer. 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, 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** force the dose knob to turn beyond 80 units. **Do not** push the purple injection button when turning the dose knob.



Step 5. Select and clean the injection site

- A** Select the injection site as explained to you by your healthcare provider, clean with a new alcohol wipe and let your skin dry before you inject your dose.
- Injection sites include your arms, hips, thighs, buttocks and abdomen. You should change your injection site for each injection.



Step 6. Inject your dose

- A** 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. **Do not** inject with the needle at an angle.
 - C** Press the purple injection button all the way in. The white dose knob will turn and you will hear "clicks" as you press down.
 - D** Hold the purple injection button down for 10 seconds after the dose window shows "0" to make sure all of the 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.
- 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.



Step 7. After your injection

- A** Take the outer needle cap that you had saved in step 2D, hold it at the widest part and carefully cover the needle without touching it.
- B** Squeeze the wide part of the outer needle cap and unscrew the needle in an anti-clockwise (left) direction. 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 for instructions on disposal)
- D** Replace the pen cap over the cartridge.
- E** Store the pen at room temperature (under 30°C). **Do not** store the pen with a used needle attached.



Step 8. Disposal

- Put your used needle in a sharps disposal container right away after use. **Do not** throw away (dispose of) loose needles in your household waste.
- If you do not have a 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,

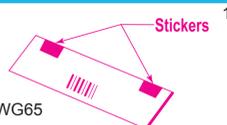


- Upright and stable during use,
- Leak-resistant, and
- Properly labelled to warn of hazardous waste inside the container.

The used pen may be discarded in your household waste after you have removed the needle.

Pen care

- Always carry an extra insulin pre-filled pen injector as recommended by your healthcare provider in case your pen gets lost or damaged.
- Always use a new sterile disposable needle for each injection.
- Keep your pen away from moisture, dust, direct sunlight and places where the temperature may get too high or low (see storage section at the beginning of these instructions).
- 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 described in Step 7, and discard the pen or return it to the pharmacist. Use a new pen instead.



Artwork Approval sheet

Product Brand Name	Semglee	Market	Singapore	
Product Generic Name	Glargine	Sales / PS	Sales	
Strengths	100 U/mL	Pack Size	NA	
Type of Component	IFU	Component Size	750 x 440 mm	
Substrate	XXXXXXXXXX			
Design & Style	PRC			
Foil Width	NA	Blister size	NA	
Current Site material code	BM/0247/01	Superseded Site material code	NA	
Pantone Numbers / Colour Scheme				
Reason for Issuance	New Component / Revise Component			
Reason for Revision	NA			
Mylan Approvals				
Packaging Coordinator	Business Development	Marketing	Regulatory Affairs	Quality Assurance
Third Party Site Approvals				
Packaging Development	Production	Regulatory Affairs	Quality Assurance	