Inject the medicine in the cartridge looks clear and colorless.

Step 1. Inspect your pen

Each time you use the pen

• Make sure the pen is sealed and that the sticker sealing the carton is not broken. After been changed. You may give other people a serious infection or get a serious infection 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.

You healthcare provider should show you a Semglee® prefilled pen before you use it for the first time.

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

Semglee® is disposable prefilled injector that contains a total of 300 units of insulin glargine. Each pen contains more than one dose of insulin. 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 your medication more than once.

Do not share your Semglee® pen with other people, even if the needle has not 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 someone who uses a Semglee® single-patient-use 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 removing the carton look at the pen to make sure that it looks new and is not broken.

Pen assembly

1. Prefilled pen with 3 mL cartridge

Step 1. Inspect your pen

Inspect the pen. Check the purple and white label on the pen to make sure:

• The correct insulin type.

• The expiration date has not passed.

• Hold the pen body with 1 hand. With the other hand pull off the pen (put the outer needle cap sideways as this may cause the needle to break). (See Figure A).

• Inspect the insulin through the cartridge holder to make sure:

There are no crosses, bubbles or leaks inside the cartridge holder.

• Wipe the rubber seal at the end of the cartridge with a new alcohol wipe.

Step 2. Attach a new needle

• Take a new sterile disposable needle and peel off the protective tab (See Figure B). Do not use the needle if the protective tab is peeled off or missing.

• With the pen body facing upwards, attach the outer needle cap straight onto the cartridge holder as shown. Do not turn the outer needle cap. If you turn the outer needle cap you could cause the needle to bend or become damaged (See Figure C).

• Turn the outer needle cap in a clockwise (right) direction until you hear a ‘click’. (See Figure D). (This indicates that the outer needle cap is securely attached to the pen body.)

• Carefully pull out the outer needle cap and put it off to the side (See Figure E).

• Re-set the duration. (If you need to move the needle away from the insulin cartridge, set the duration to 0).

With the pen needle facing upwards, press the injection button after 28 days.

Step 3. Prime your pen needle

Always prime a new pen needle before each injection.

Step 3. Prime your pen needle

Step 3. Prime your pen needle

Step 4. Select your dose

Step 4. Select your dose

Turn the white dose knob until the yellow dose pointer lines up with your required dose.

The pen dial 1 unit at a time.

The white dose knob does not rotate more than 360 degrees. If you peaked a dose greater than 80 units you should give it in two or more injections.

The eXact numbers are shown as lines in between the even numbers. (See Figure F).

The number of units left in the pen (See Figure G).

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

In-use Pen

You can correct the dose by turning the dose knob in either direction until the correct dose line up with the yellow dose pointer.

Do not use your pen if the number of units left in the pen is zero.

• In-use Pen

Do not push the purple injection button while you are turning the dose knob.

• Do not push your dose by counting the clicks because you may dial the wrong dosing.

• The even numbers are printed on the odd (See Figure H).

• You can correct the dose by turning the dose knob either direction until the correct dose line up with the yellow dose pointer.

• Do not use your pen if the number of units left in the pen is zero.

While using the pen, store it at room temperature up to 86°F (30°C).

If your unused pen is stored at room temperature and you want to use it after the expiration date.

The semglee® dials 1 unit at a time.

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.

Customer support

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

• Wash your hands with soap and water before using your pen.

• Check that the medicine in the cartridge looks clear and colorless. Do not use the pen if the medicine has clumps or color.

• Always use a new sterile disposable needle for each injection.

• Keep an injection site that your healthcare provider has shown you.

Step 7. After your injection

Step 7. After your injection

• Do not push the purple injection button while you are turning the dose knob.

• Do not push your dose by counting the clicks because you may dial the wrong dosing.

• The even numbers are printed on the odd (See Figure H).

• You can correct the dose by turning the dose knob either direction until the correct dose line up with the yellow dose pointer.

• Do not push the purple injection button while you are turning the dose knob.

• Do not push your dose by counting the clicks because you may dial the wrong dosing.

• The even numbers are printed on the odd (See Figure H).

• You can correct the dose by turning the dose knob either direction until the correct dose line up with the yellow dose pointer.

• Do not push the purple injection button while you are turning the dose knob.

• Do not push your dose by counting the clicks because you may dial the wrong dosing.

• The even numbers are printed on the odd (See Figure H).

• You can correct the dose by turning the dose knob either direction until the correct dose line up with the yellow dose pointer.

• Do not push the purple injection button while you are turning the dose knob.

• Do not push your dose by counting the clicks because you may dial the wrong dosing.
Read the Instructions for Use carefully before using SEMGLEE prefilled pen and each time you get a new pen. These may be minor changes. 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 pen, ask for help from someone trained to use this pen.

Your healthcare provider should show you how to use the SEMGLEE prefilled pen right 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 how your insulin works.

SEMGLEE is disposable prefilled pen that contains a total of 300 units of insulin glargine U300. Each pen contains more than one dose of insulin. 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 extra doses

Do not share your SEMGLEE prefilled pen with other people, even if the needle has never been changed. You may give other people a serious infection or get a serious infection from them.

People who are blind or have visual problems should use SEMGLEE single-patient-use prefilled pen without help from another person. SEMGLEE single-patient-use is a 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 inhaler 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.

Check the expiration date on the pen label. Do not use the pen after the expiration date.

Check that the insulin in the pen cartridge looks clear and colorless. Do not use the pen if the medicine in the cartridge looks cloudy 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

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.

Hold the pen body with 1 hand. With the other hand pull off the insulin cartridge. Put the insulin cartridge back on when you are ready to use the pen.

The insulin looks clear and colorless.

There are no cracks, breaks or leaks around the cartridge holder.

Wipe the rubber seal on the front of the cartridge with a new alcohol wipe.

Step 2. Attach a new needle

Take a new sterile disposable needle and peel off the protective tab (See Figure e). Do not use the needle if the protective tab is missing or torn.

While holding the pen body facing upwards, attach the outer needle cap straight on to the cartridge holder as shown. Do not unscrew the needle cap. The cartridge and needle will release the insulin if the needle cap is not screwed on tightly.

Carefully pull the outer needle cap and pull it off to the side (See Figure e). Do not twist the needle cap. You will need the outer needle cap later.

Carefully pull the inner needle cap and throw it away in the sharps container (See Figure f).

Do not inject where the skin has a pimple, scar or lesion.

Step 3. Prime your pen needle

Always prime a new pen needle before each injection.

Turn the white dose knob to 2 dose units (See Figure h).

If you accidentally turn past 2 units, turn back the dose knob in the opposite direction to the correct number of units.

Prime the pen body facing upwards with 1 hand.

Tap the cartridge gently with your finger to help any large air bubbles to bubble to the top of the cartridge (See Figure i).

Small bubbles may still be visible. This is normal.

Check the dosage window for each unit (See Figure j). The white dose knob will turn and you will hear “clicks.”

Step 4. Select your dose

Check that the dose window shows “0.”

Turn the white dose knob until the yellow dose pointer lines up with your required dose.

The pen dial 1 unit at a time.

Make the white plunger tip turn red as you turn it and it will stop when it comes in contact with the cartridge holder.

Do not push the purple injection button while you are turning the dose window.

Do not rotate your pen by counting the clicks because you may dial in the wrong dose.

The even numbers are printed on the dial (See Figure k).

If you can not find the correct dose by turning the dose knobs in either direction until the correct dose line up with the yellow dose pointer.

Do not use the white dose knob if it is beyond 80 units. If you exceed a dose greater than 80 units you should give it two or more injections.

The more numbers of units on the dial the lower the dose.

The less numbers of units on the dial the higher the dose.

Inject the amount of insulin in your pen and use a new pen to give the rest of your dose or your insulin in a new pen and inject the full dose.

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

Step 5. Inject your dose

Select the injection site as explained to you by your healthcare provider. SEMGLEE is injected under the skin (subcutaneous) of your stomach area (abdominal area), thigh, or upper arm. Before you give your injection:

• There are no cracks, breaks or leaks around the cartridge holder.
• The insulin looks clear and colorless.

Clean with a new alcohol wipe and let your skin dry before you inject your dose.

Inject insulin exactly as your healthcare provider has shown you.

Change your insulin sites as the area you choose for each dose-to-reduce your risk of getting skin irritation (aka, "pinch") or localized redness/amylodoids (painful at the injection site).

Do not inject where the skin has a pimple, scar or lesion.

Step 6. Dispose of your pen

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 that require special clean techniques and ways to store and dispose of sharps containers. For details 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/sharps/disposal

Do not dispose of a used sharps disposal container in your household trash unless you have been told it is safe to do so.

If you do not have an FDA-cleared sharps disposal container right after use. Do not throw away disposed of needles in your household trash.

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The Instructions for Use have been approved by the Food and Drug Administration. Approved 3/3/2020

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