

Instructions for use

ABASAGLAR 100units/mL Tempo Pen solution for injection in a pre-filled pen insulin glargine



PLEASE READ THESE INSTRUCTIONS BEFORE USE

Read the instructions for use before you start using ABASAGLAR and each time you get another ABASAGLAR Tempo Pen. There may be new information. This information does not take the place of talking to your healthcare professional about your medical condition or your treatment.

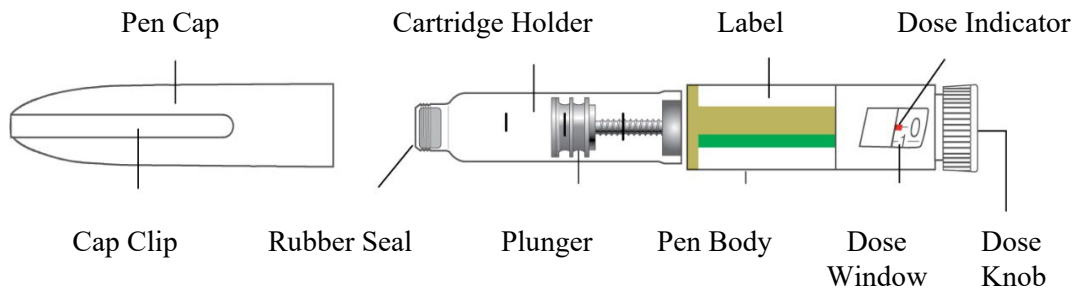
ABASAGLAR Tempo Pen (“Pen”) is a disposable prefilled pen containing 300 units (3 mL) of insulin glargine. You can give yourself multiple doses using one pen. The pen dials 1 unit at a time. You can give from 1 to 80 units in a single injection. **If your dose is more than 80 units, you will need to give yourself more than one injection.** The plunger only moves a little with each injection, and you may not notice that it moves. The plunger will only reach the end of the cartridge when you have used all 300 units in the pen.

The Tempo Pen is designed to work with the Tempo Smart Button. The Tempo Smart Button is an optional product that can be attached to the Tempo Pen dose knob and aids in transmitting Abasaglar dose information from the Tempo Pen to a compatible mobile application. The Tempo Pen injects insulin with or without the Tempo Smart Button attached. Your Smart Button must be attached to a Tempo Pen to record or transfer dose data. Push the Smart Button straight down on the dose knob until you hear a snap or feel the Smart Button snap into place. To transmit data to the mobile application, follow the instructions provided with the Tempo Smart Button and the instructions with the mobile application.

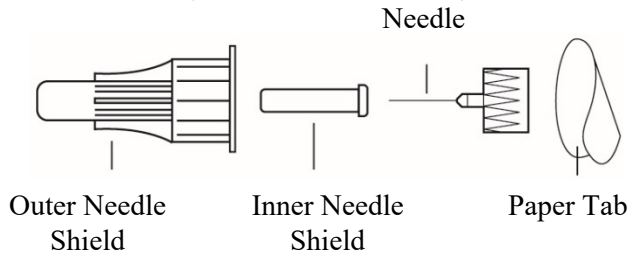
Do not share your pen with other people, even if the needle has been changed. Do not reuse or share needles with other people. You may give an infection to them or get an infection from them.

This pen is not recommended for use by the blind or visually impaired without the help of someone trained to use the pen.

Tempo Pen Parts



Pen Needle Parts (Needles Not Included)



Dose Knob



How to recognise your ABASAGLAR Tempo pen:

- Pen colour: Light grey
- Dose Knob: Light grey
- Labels: Light grey with green colour bars

Supplies needed to give your injection:

- Tempo Pen containing your insulin
- Tempo Pen compatible needle (BD [Becton, Dickinson and Company] pen needles recommended)
- Swab

Needles and swab are not included.

Preparing your pen

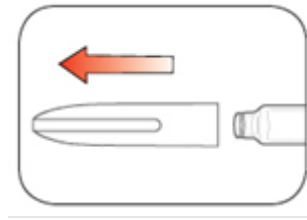
- Wash your hands with soap and water.
- Check the pen to make sure you are taking the right type of insulin. This is especially important if you use more than 1 type of insulin.
- **Do not** use your pen past the expiration date printed on the pen label or for more than 28 days after you first start using the pen.
- Always use a **new needle** for each injection to help prevent infections and blocked needles.

Step 1:

- Pull the pen cap straight off.
 - **Do not** remove the pen label.
- Wipe the rubber seal with a swab.

ABASAGLAR should look clear and colourless.

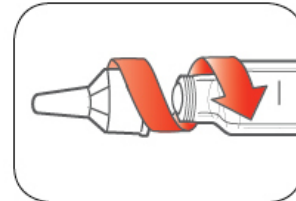
Do not use if it is cloudy, coloured, or has particles or clumps in it.

**Step 2:**

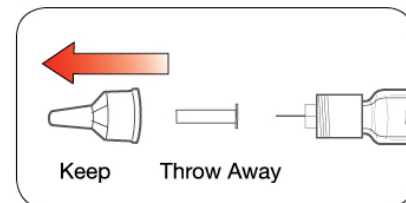
- Select a new needle.
- Pull off the paper tab from the outer needle shield.

**Step 3:**

- Push the capped needle straight onto the pen and twist the needle on until it is tight.

**Step 4:**

- Pull off the outer needle shield. **Do not** throw it away.
- Pull off the inner needle shield and throw it away.

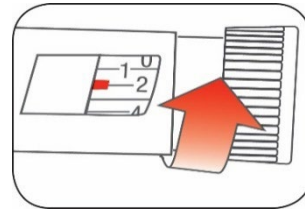


Priming your pen**Prime before each injection.**

- Priming your pen means removing the air from the needle and cartridge that may collect during normal use and ensures that the pen is working correctly.
- If you **do not** prime before each injection, you may get too much or too little insulin.

Step 5:

- To prime your pen, turn the dose knob to select 2 units.



Step 6:

- Hold your pen with the needle pointing up. Tap the cartridge holder gently to collect air bubbles at the top.

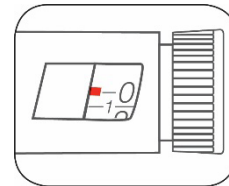
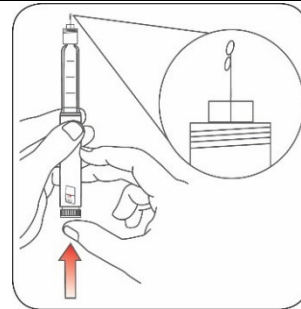


Step 7:

- Continue holding your pen with needle pointing up. Push the dose knob in until it stops, and “0” is seen in the dose window. Hold the dose knob in and count to 5 slowly.

You should see insulin at the tip of the needle.

- If you **do not** see insulin, repeat the priming steps, but not more than 4 times.
- If you **still do not** see insulin, change the needle and repeat the priming steps.



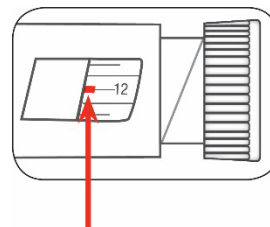
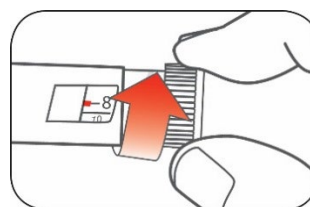
Small air bubbles are normal and will not affect your dose.

Selecting your dose

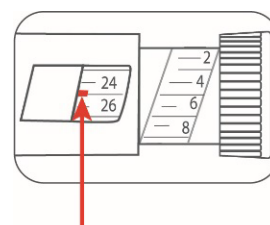
- You can give from 1 to 80 units in a single injection.
- If your dose is more than 80 units, you will need to give more than one injection.
 - If you need help deciding how to divide up your dose, ask your healthcare professional.
 - You should use a new needle for each injection and repeat the priming step.

Step 8:

- Turn the dose knob to select the number of units you need to inject. The dose indicator should line up with your dose.
 - The pen dials 1 unit at a time.
 - The dose knob clicks as you turn it.
 - **DO NOT** dial your dose by counting the clicks because you may dial the wrong dose.
 - The dose can be corrected by turning the dose knob in either direction until the correct dose lines up with the dose indicator.
 - The **even** numbers are printed on the dial.
 - The **odd** numbers, after the number 1, are shown as full lines.
- **Always check the number in the dose window to make sure you have dialled the correct dose.**



(Example: 12 units shown in the dose window)



(Example: 25 units shown in the dose window)

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- The pen will not let you dial more than the number of units left in the pen.
 - If you need to inject more than the number of units left in the pen, you may either:
 - inject the amount left in your pen and then use a new pen to give the rest of your dose, **or**
 - get a new pen and inject the full dose.
 - It is normal to see a small amount of insulin left in the pen that you cannot inject.

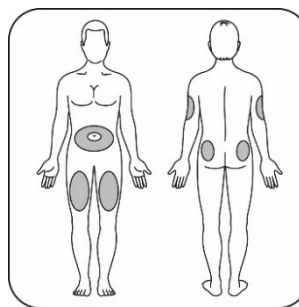
Giving your injection

- Inject your insulin as your healthcare professional has shown you.
- Change (rotate) your injection site for each injection.
- **Do not** try to change your dose while injecting.

Step 9:

Choose your injection site.

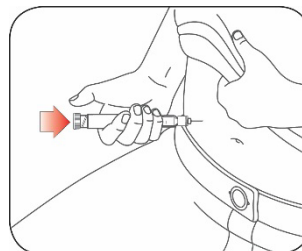
- ABASAGLAR is injected under the skin (subcutaneously) of your stomach area, buttocks, upper legs or upper arms.
- Prepare your skin as recommended by your healthcare professional.



Step 10:

- Insert the needle into your skin.

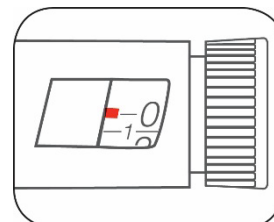
- Push the dose knob all the way in.
- Continue to hold the dose knob in and **slowly count** to 5 before removing the needle.



Do not try to inject your insulin by turning the dose knob. You will **NOT** receive your insulin by turning the dose knob.

Step 11:

- Pull the needle out of your skin.
 - A drop of insulin at the needle tip is normal. It will not affect your dose.
- Check the number in the dose window
 - If you see “0” in the dose window, you have received the full amount you dialled.
 - If you do not see “0” in the dose window, **do not** redial. Insert the needle into your skin and finish your injection.
 - If you **still do not** think you received the full amount you dialled for your injection, **do not start over or repeat that injection.** Monitor your blood glucose as instructed by your healthcare professional.
 - If you normally need to give 2 injections for your full dose, be sure to give your second injection.



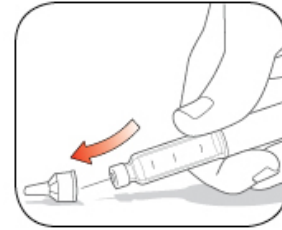
The plunger only moves a little with each injection, and you may not notice that it moves.

If you see blood after you take the needle out of your skin, press the injection site lightly with a piece of gauze or swab. **Do not** rub the area.

After your injection

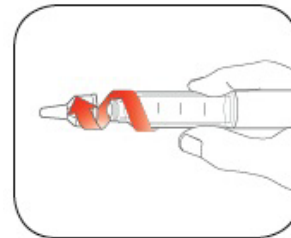
Step 12:

- Carefully replace the outer needle shield.



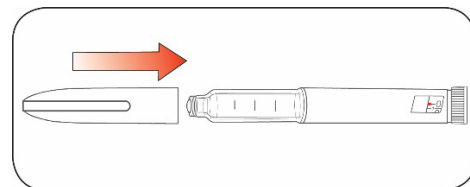
Step 13:

- Unscrew the capped needle and dispose of it as described below (see **Disposing of pens and needles** section).
- **Do not** store the pen with the needle attached to prevent leaking, blocking the needle, and air from entering the pen.



Step 14:

- Replace the pen cap by lining up the cap clip with the dose indicator and pushing straight on.



Disposing of pens and needles

- Put used needles in a closable, puncture-resistant sharps container.
- **Do not** recycle the filled sharps container.
- Ask your healthcare professional about options to dispose of the pens and sharps container properly.
- The directions regarding needle handling are not intended to replace local, healthcare professional or institutional policies.

Storing your pen

Unused pens

- Store unused pens in the refrigerator at (2 °C to 8 °C).
- **Do not** freeze ABASAGLAR. **Do not** use if it has been frozen.
- Unused pens may be used until the expiration date printed on the label, if the pen has been kept in the refrigerator.

In-use pen

- Store the pen you are currently using at room temperature [below (30 °C)] and away from dust, food and liquids, heat and light.
- Throw away the pen you are using after 28 days, even if it still has insulin left in it.

General information about the safe and effective use of your pen

- **Keep your pen and needles out of the sight and reach of children.**
- **Do not** use your pen if any part looks broken or damaged.
- Always carry an extra pen in case yours is lost or damaged.

Troubleshooting

- If you cannot remove the pen cap, gently twist the cap back and forth, and then pull the cap straight off.
- If the dose knob is hard to push:
 - Pushing the dose knob more slowly will make it easier to inject.
 - Your needle may be blocked. Put on a new needle and prime the pen.
 - You may have dust, food, or liquid inside the pen. Throw the pen away and get a new pen. You may need to get a prescription from your healthcare professional.

If you have any questions or problems with your ABASAGLAR Tempo Pen, contact your healthcare professional for help.

This leaflet was last revised in June 2021

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