

Instructions for Use

BASAGLAR[®] KwikPen[®]

(insulin glargine)

injection, for subcutaneous use

100 units/mL, 3 mL single-patient-use pen



Read the Instructions for Use before you start using BASAGLAR and each time you get another BASAGLAR[®] KwikPen[®]. 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.

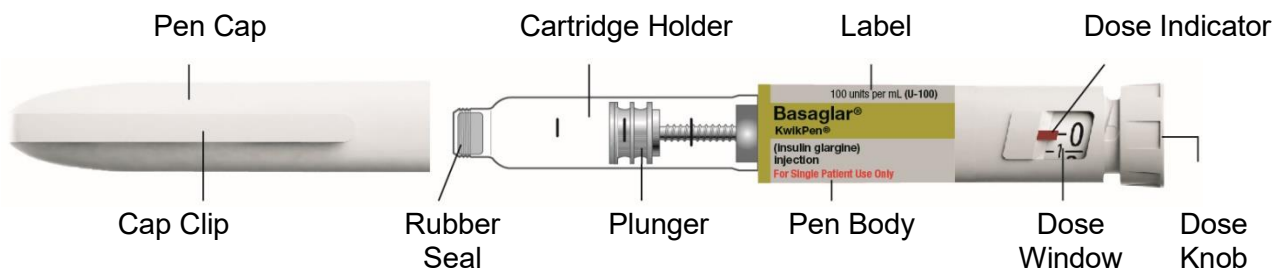
Do not share your BASAGLAR KwikPen with other people, even if the needle has been changed. You may give other people a serious infection or get a serious infection from them.

BASAGLAR KwikPen (“Pen”) is a disposable single-patient-use prefilled pen containing 300 units (3mL) of BASAGLAR. One pen contains multiple doses of medicine.

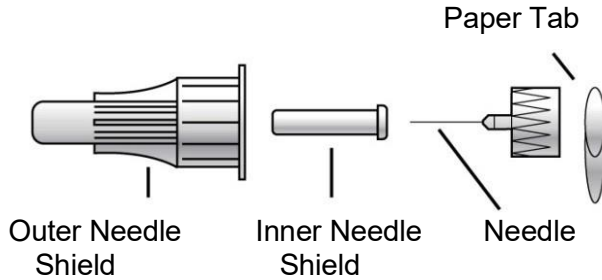
- Your healthcare provider will tell you how many units to give as your dose and how to inject your prescribed dose of medicine.
- You can give a dose of 1 to 80 units in a single injection.
- **If your prescribed dose is more than 80 units, you will need to give yourself more than 1 injection.**
- The plunger only moves a little with each injection, and you may not notice that it moves. When the plunger reaches the end of the cartridge, you have used all 300 units in the Pen.

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

KwikPen Parts



Pen Needle Parts (Needles Not Included)



Dose Knob with green ring



How to recognize your BASAGLAR KwikPen

- Pen color: Light grey
- Dose Knob: Light grey with green ring on the end
- Labels: Light grey with green color bars

Supplies needed to give your injection

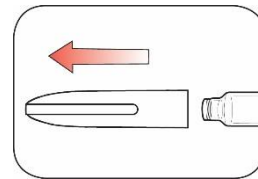
- BASAGLAR KwikPen
- KwikPen compatible Needle (Becton, Dickinson and Company Pen Needles recommended)
- Alcohol swab

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 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. **Do not reuse or share your needles with other people. You may give other people a serious infection or get a serious infection from them.**

Step 1:

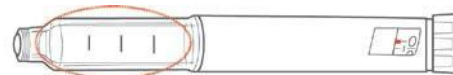
- Pull the Pen Cap straight off.
 - **Do not** remove the Pen Label.
- Wipe the Rubber Seal with an alcohol swab.



Step 2:

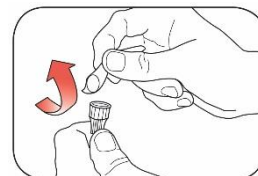
- **Check the liquid in the Pen.**

BASAGLAR should look clear and colorless. **Do not** use if it is cloudy, colored, or has particles or clumps in it.



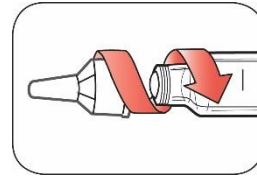
Step 3:

- Select a new Needle.
- Pull off the Paper Tab from the Outer Needle Shield.



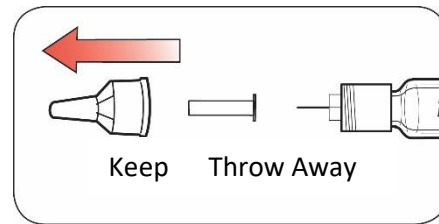
Step 4:

- Push the capped Needle straight onto the Pen and twist the Needle on until it is tight.



Step 5:

- Pull off the Outer Needle Shield. **Do not** throw it away.
- Pull off the Inner Needle Shield and throw it away.

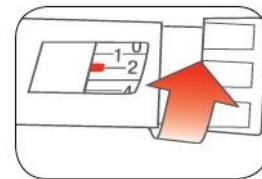


Priming your Pen**Prime before each injection.**

- Priming means removing the air from the Needle and Cartridge that may collect during normal use. It is important to prime your Pen before each injection so that it will work correctly.
- If you **do not** prime before each injection, you may get too much or too little insulin.

Step 6:

- To prime your Pen, turn the Dose Knob to **select 2 units**.



Step 7:

- Hold your Pen with the Needle pointing up. Tap the Cartridge Holder gently to collect air bubbles at the top.



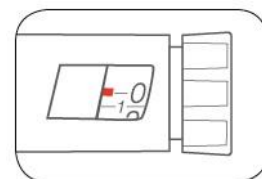
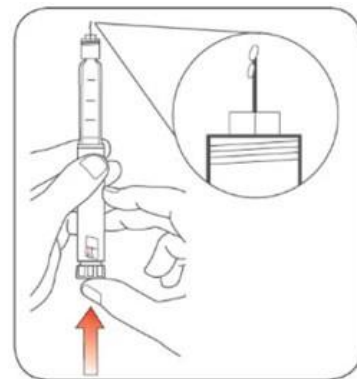
Step 8:

- 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.



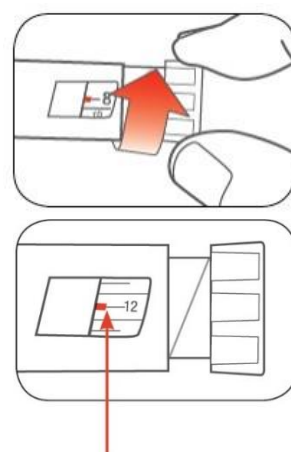
Selecting your dose

- If your dose is more than 80 units, you will need to give more than 1 injection.

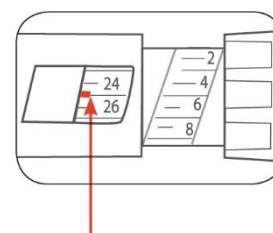
- Talk to your healthcare provider about how to give your dose.
- Use a new Needle for each injection and repeat the priming step.

Step 9:

- 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 dialed the correct dose.**



(Example: 12 units shown in the Dose Window)



(Example: 25 units shown in the Dose Window)

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 can not inject.

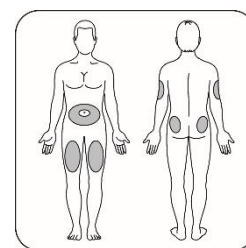
Giving your injection

- Inject your insulin 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 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.
- **Do not** try to change your dose while injecting.

Step 10:

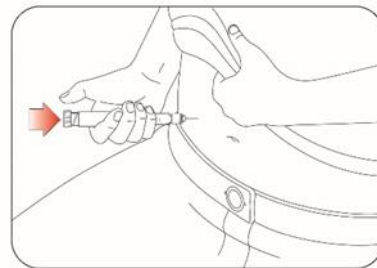
Choose your injection site.

- BASAGLAR is injected under the skin (subcutaneously) of your stomach area, buttocks, upper legs or upper arms.
- Wipe the skin with an alcohol swab, and let the injection site dry before you inject your dose.



Step 11:

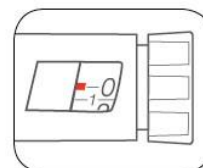
- Insert the Needle into your skin.
- Push the Dose Knob all the way in.
- Continue to hold the Dose Knob in and **slowly count to 5** before removing the needle.



Note: Do not try to inject your insulin by turning the Dose Knob. You will **not** receive your insulin by turning the Dose Knob.

Step 12:

- 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 dialed.
 - If you do not see “0” in the Dose Window you did not receive your full dose. 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 dialed for your injection, do not start over or repeat that injection. Monitor your blood glucose and call your healthcare provider for further instructions.
 - If you normally need to give 2 injections for your full dose, be sure to give your second injection.



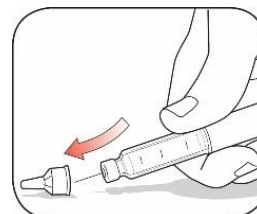
The plunger only moves a little with each injection, and you may not notice that it moves.

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

After your injection

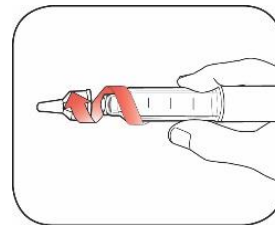
Step 13:

- Carefully replace the Outer Needle Shield.



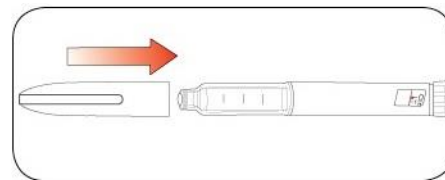
Step 14:

- Unscrew the capped Needle and throw it away (see **Disposing of Pens and Needles** section below).
- Do not store the Pen with the Needle attached to prevent leaking, blocking the Needle, and air from entering the Pen.



Step 15:

- Replace the Pen Cap by lining up the Cap Clip with the Dose Indicator and pushing straight on.



Disposing of Pens and Needles

- Put your used needles in a 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 a FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a 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 disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal 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's website at: <http://www.fda.gov/safesharpsdisposal>
- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.
- The used Pen may be discarded in your household trash after you have removed the needle.

Storing your BASAGLAR KwikPen**Unused Pens**

- Store unused Pens in the refrigerator at 36°F to 46°F (2°C to 8°C).
- **Do not** freeze BASAGLAR. **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 [up to 86°F (30°C)] and away from 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.**
- **Always** use a new needle for each injection.
- **Do not share your Pen or needles with other people. You may give other people a serious infection or get a serious infection from them.**
- **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 can not 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.

If you have any questions or problems with your BASAGLAR KwikPen, contact Lilly at 1-800-LillyRx (1-800-545-5979) or call your healthcare provider for help. For more information on BASAGLAR KwikPen and insulin, go to www.basaglar.com.



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www.basaglar.com

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

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Manufactured by:
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Indianapolis, IN 46285, USA
US License Number 1891

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BASAGLAR KwikPen meets the current dose accuracy and functional requirements of ISO 11608-1.

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