

INSTRUCTIONS FOR USE
REZVOGLAR™ KwikPen® (REHZ-voh-glahr)
(insulin glargine-aglr)
injection, for subcutaneous use
3 mL Single-Patient-Use PREFILLED-PEN: 100 units/mL (U-100)

Read these Instructions for Use before you start taking the REZVOGLAR KwikPen (“Pen”) and each time you get a new REZVOGLAR 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 REZVOGLAR 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.

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

REZVOGLAR KwikPen is a disposable prefilled pen used to inject REZVOGLAR. Each REZVOGLAR KwikPen has 300 units of insulin which can be used for multiple injections. You can select doses from 1 to 80 units in steps of 1 unit. The Pen plunger moves with each dose, but you may not notice that it moves. The plunger will only move to the end of the cartridge when 300 units of REZVOGLAR have been given.

Important Information You Need to Know Before Injecting REZVOGLAR

- **Do not** use your Pen if it is damaged or if you are not sure that it is working properly.
- **Do not** use a syringe to remove REZVOGLAR from your Pen.
- **Do not reuse Needles.** If you do, you might get the wrong dose of REZVOGLAR and/or increase the chance of getting an infection.
- Always perform a safety test (prime the REZVOGLAR KwikPen) (see **Step 3**).
- Always carry a spare Pen and spare Needles in case of loss or damage.
- Change (rotate) your injection sites within the area you choose for each dose (see “**Places to inject**”).

Learn to Inject

- Talk with your healthcare provider about how to inject before using your Pen.
- Ask for help if you have problems handling the Pen, for example if you have problems with your sight.
- Read all these instructions before using your Pen. If you do not follow all these instructions, you may get too much or too little insulin.

Need Help?

If you have any questions about your Pen or about diabetes, ask your healthcare provider, or go to www.rezvoglar.com or call Eli Lilly and Company at 1-800-545-5979.

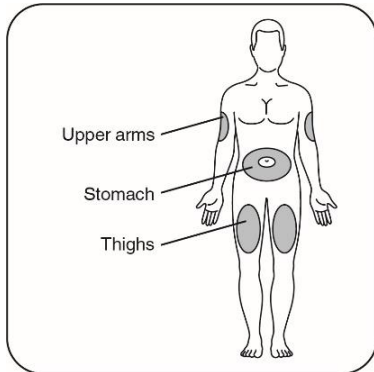
Extra Items You Will Need

- a new sterile Pen Needle (see **Step 2**).
- an alcohol swab.
- a puncture-resistant container for used Needles and Pens (See “**Throwing your Pen away**”).

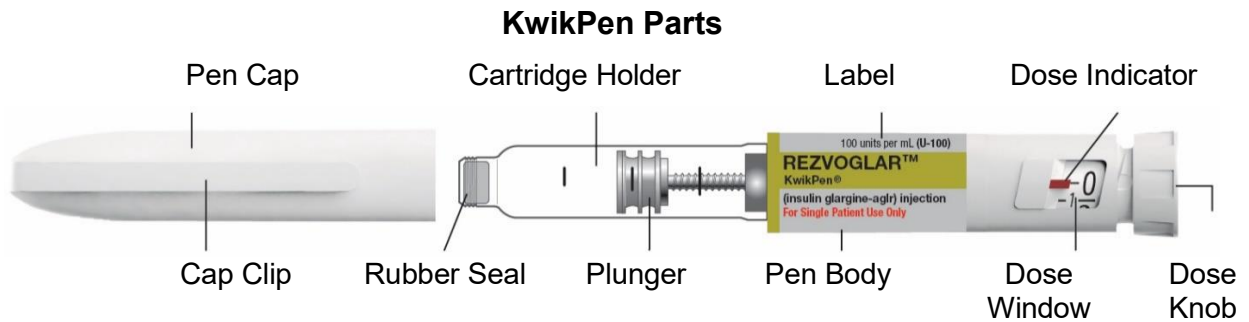
Places to inject

- Inject your insulin exactly as your healthcare provider 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.

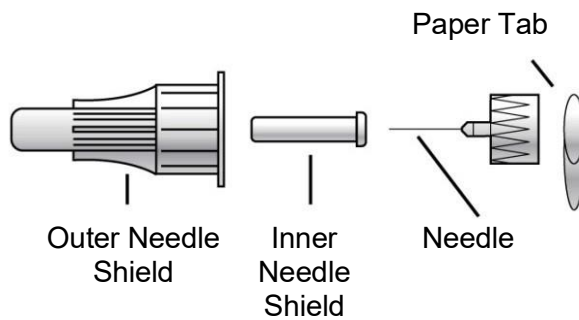
- **Do not** inject where the skin has pits, is thickened, or has lumps.
- **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.
- **Do not** try to change your dose while injecting.



Get to know your Pen



Pen Needle Parts (Needles Not Included)



Dose Knob with green ring



Step 1: Check your Pen

Take a new Pen out of the refrigerator at least **1** hour before you inject. Cold insulin is more painful to inject.

1A Check the name and expiration date on the label of your Pen. The REZVOGLAR KwikPen is light grey with a light grey Dose Knob that has a green ring on the end. The label on the Pen is light grey with green color bars.

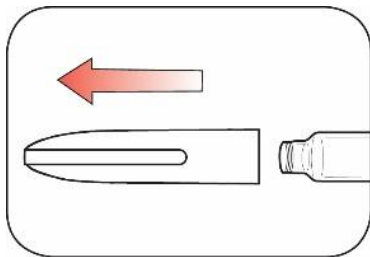
- Make sure you have the correct insulin.



- **Do not** use your Pen after the expiration date.

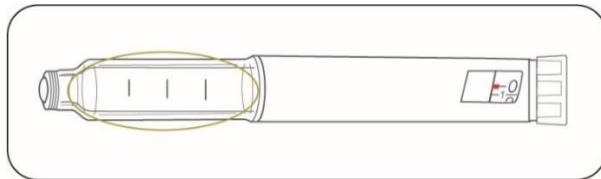


1B Pull off the Pen Cap.

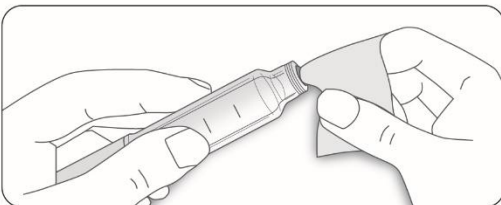


1C Check that the insulin is clear.

- **Do not** use the Pen if the insulin looks cloudy, colored or contains particles.



1D Wipe the Rubber Seal with an alcohol swab.



If you have other injector pens:

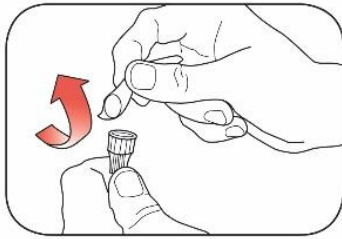
- Making sure you have the correct medicine is especially important if you have other injector pens.

Step 2: Attach a new Needle

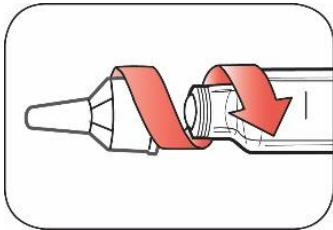
- **Do not** re-use Needles. Always use a new sterile Needle for each injection. This helps stop blocked Needles, contamination, and infection.

Only use Needles that are compatible with REZVOGLAR KwikPen. Becton, Dickinson and Company (BD) Pen Needles are recommended. These are sold separately. Contact your healthcare provider for further information.

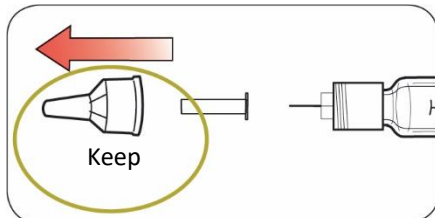
2A Take a new Needle and peel off the Paper Tab.



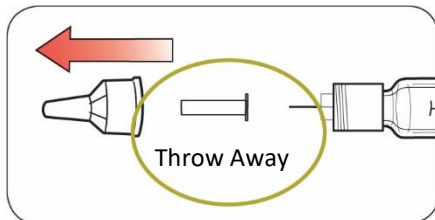
2B Keep the Needle straight and screw it onto the Pen until fixed. Do not over-tighten.



2C Pull off the Outer Needle Shield. Keep this for later.



2D Pull off the Inner Needle Shield and throw away.



Handling Needles

- Take care when handling Needles to prevent needle-stick injury and cross-infection.

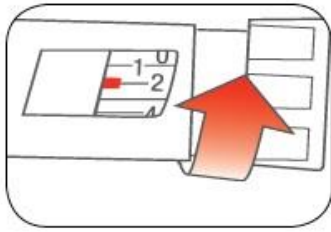
Step 3: Do a safety test (Prime your REZVOGLAR KwikPen)

Always do a safety test (prime) before each injection to:

- Check your Pen and the Needle to make sure they are working properly.

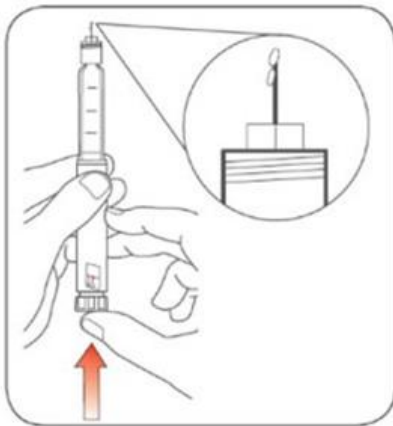
- Make sure that you get the correct REZVOGLAR dose.

3A Select 2 units by turning the Dose Knob until the Dose Indicator is at the 2 mark.



3B Press the Dose Knob all the way in.

When insulin comes out of the Needle tip, your Pen is working correctly:



If no insulin appears:

- You may need to repeat this step up to 4 times before seeing insulin.
- If no insulin comes out after the fourth time, the Needle may be blocked. If this happens:
 - change the Needle (see **Step 6** and **Step 2**),
 - then repeat the safety test (prime) (**Step 3**).
- **Do not** use your Pen if there is still no insulin coming out of the Needle tip. Use a new Pen.
- **Do not** use a syringe to remove insulin from your Pen.

If you see air bubbles:

- You may see air bubbles in the insulin. This is normal, they will not harm you.

Step 4: Select the dose

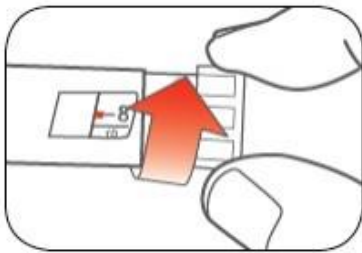
Do not select a dose or press the Dose Knob without a Needle attached. This may damage your Pen.

4A Make sure a Needle is attached and the dose is set to "0".



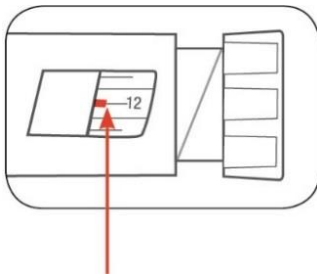
4B Turn the Dose Knob until the Dose Indicator lines up with your dose.

- If you turn past your dose, you can turn back down.
- The Dose Knob clicks as you turn it. Do not dial your dose by counting the clicks because you may dial the wrong dose.
- If there are not enough units left in your Pen for your dose, the Dose Indicator will stop at the number of units left.
- If you cannot select your full prescribed dose, use a new Pen or inject the remaining units and use a new Pen to complete your dose.



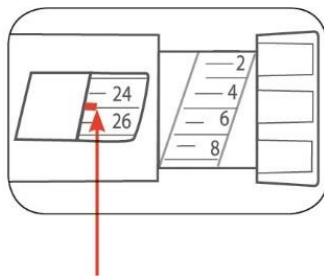
How to read the Dose Window

Even numbers are shown in line with Dose Indicator.



(Example: 12 units shown in the Dose Window)

Odd numbers, after the number 1, are shown as a line between even numbers.



(Example: 25 units shown in the Dose Window)

Units of REZVOGLAR in your Pen:

- Your Pen contains a total of **300** units of REZVOGLAR. You can select doses from **1** to **80** in steps of **1** unit. Each Pen contains more than 1 dose.
- You can see roughly how many units of insulin are left by looking at where the Plunger is on the insulin scale.

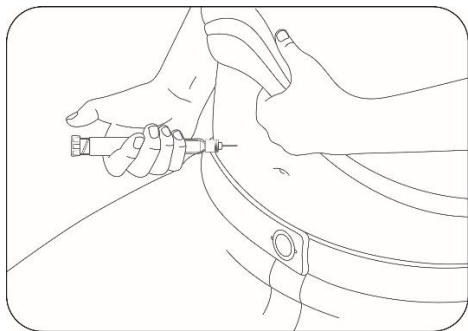
Step 5: Injecting Your REZVOGLAR Dose

If you find it hard to press the Dose Knob in, **do not** force it as this may break your Pen. See the section below for help.

5A Choose a place to inject as shown in the picture above.

5B Push the Needle into the skin as shown by your healthcare provider.

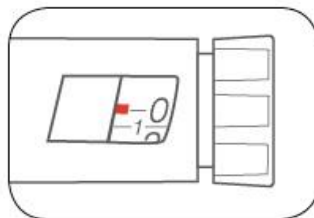
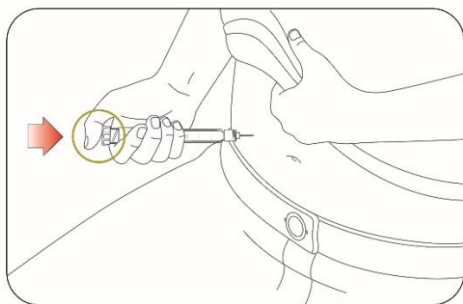
Do not touch the Dose Knob yet.



5C Place your thumb on the Dose Knob. Then press all the way in and hold.

5D Keep the Dose Knob held in and when you see "0" in the Dose Window, slowly count to 5.

- This will make sure you get your full dose.
- **Do not** try to inject your insulin by turning the Dose Knob. You will **not** receive your insulin by turning the Dose Knob.



5E After holding and slowly counting to 5, release the Dose Knob. Then remove the Needle from your skin.

- 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 the injection. Monitor your blood glucose and call your healthcare provider for further instructions.

If you find it hard to press the Dose Knob in:

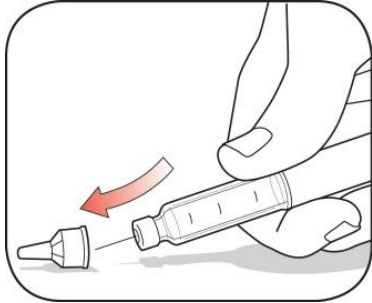
- Change the Needle (see **Step 6** and **Step 2**) then do a safety test (prime the Pen) (see **Step 3**).
- If you still find it hard to press in, get a new Pen.
- **Do not** use a syringe to remove insulin from your Pen.

Step 6: Remove the Needle

- Take care when handling Needles to prevent needle-stick injury and cross-infection.

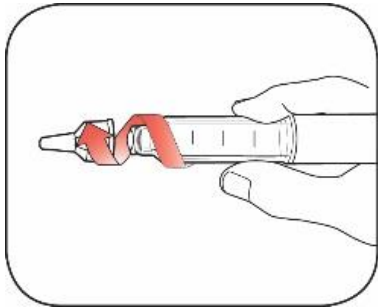
- **Do not** put the Inner Needle Shield back on.

6A Leave the Outer Needle Shield on a flat surface. Using one hand, scoop the Outer Needle Shield straight onto the Needle. When the tip is covered, lift the Needle and Pen. Then push firmly on.



6B Grip and squeeze the widest part of the Outer Needle Shield. Turn your Pen several times with your other hand to remove the Needle.

- Try again if the Needle does not come off the first time.

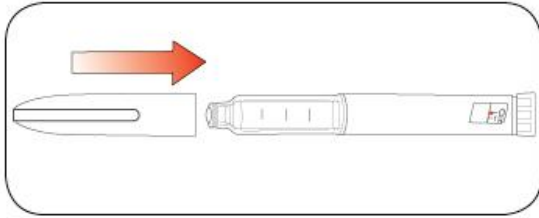


6C Throw away the used Needle in a puncture-resistant container (see "Throwing your Pen away" at the end of this Instructions for Use).



6D Put your Pen Cap back on

- Do not put the Pen back in the refrigerator.



Storing the REZVOGLAR KwikPen

Before first use

- Keep new Pens in the refrigerator between **36°F to 46°F (2°C to 8°C)**.
- **Do not** freeze. **Do not** use REZVOGLAR 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.

After first use

- Keep your Pen at room temperature **below 86°F (30°C)**.
- Keep your Pen away from heat or light.
- Store your Pen with the Pen Cap on.
- **Do not** put your Pen back in the refrigerator.
- **Do not** store your Pen with the Needle attached.
- **Keep out of the reach of children.**
- Only use your Pen for **up to 28 days** after its first use. Throw away the REZVOGLAR KwikPen you are using after 28 days, even if it still has insulin left in it.

Caring for Your REZVOGLAR KwikPen

Handle your Pen with care

- Do not drop your Pen or knock it against hard surfaces.
- If you think that your Pen may be damaged, **do not** try to fix it. Use a new one.

Protect your Pen from dust and dirt

- You can clean the outside of your Pen by wiping it with a damp cloth (water only). **Do not** soak, wash or lubricate your Pen. This may damage it.

Throwing your Pen away

- The used REZVOGLAR KwikPen may be thrown away in your household trash after you have removed the Needle.
- Put the used Needle in an FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the used 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.

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

Manufactured by:

Eli Lilly and Company

Indianapolis, IN 46285, USA

US License Number 1891

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