

Insulin Glargine

EZELIN

100 IU/mL

Pre - filled pen Solution for Injection (SC)

Anti - Diabetic

INSTRUCTION FOR USE

Single-Patient-Use Prefilled Pen

Please carefully read this instruction before use. Keep this leaflet for future reference.

Your healthcare professional has decided that Ezelin is right for you. Consult your healthcare professional about proper injection technique before using Ezelin. Read these instructions carefully before using your Ezelin.

- **Do not share your pen with others, 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 must not use Ezelin single-patient-use Prefilled Pen without help from a person trained to use it.**
- **Follow these instructions completely each time you use Ezelin to ensure that you get an accurate dose. If you do not follow these instructions you may get too much or too little insulin, which may affect your blood sugar/blood glucose level.**
- **If you are not able to follow all the instructions completely on your own, use Ezelin only if you get help from a person who is able to follow the instructions.**

Ezelin is a disposable pen for the injection of insulin. Each Ezelin contains 300 units of insulin in total. You can set doses from 1 to 60 units in steps of 1 unit. The pen plunger moves with each dose. The plunger will only move to the end of the cartridge when 300 units of insulin have been given.

Need Help?

If you have any questions about Ezelin or diabetes, always ask your healthcare professional.

For further information, you can visit our website www.kalbemed.com call 021-4287388889.

Materials needed

Included in your carton

Your Ezelin (see **Figure A**), contains a total of 300 units of insulin.

NOT included in your carton

- A new sterile needle (needles compatible with Ezelin:BD Ultra-fine", Mylife-needles, Clickfine", NovoFine,Penfine Classic, and Xiulin®). Needles are sold separately. Contact your healthcare professional for further information.
- An alcohol prep pad
- A sharps disposal container for used needles

Important information you need to know before injecting Ezelin

- To avoid mix-up of different insulin pens, **store pens with different medicine in separate areas** and read the label of your Ezelin prior to injection.
- **Do not share your 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.
- **Do not reuse needles.** Always attach a new sterile needle before each use to prevent contamination or blocked needle, which could lead to not getting your dose.
- **Do not** use your pen if it is damaged or unsure whether it is working properly.
- **Do not** select a dose or press the injection button without a needle attached.
- Always have a spare Ezelin in case your pen is lost or damaged.
- Always perform the safety test (see Step 3. Perform a safety test) before each injection
- If your injection is given by another person, special caution must be taken by this person to avoid accidental needle injury and transmission of infection.

Step 1. Check the pen and insulin

If your Ezelin is in the refrigerator, take it out 1 to 2 hours before you inject to allow it to reach room temperature, you will be uncomfortable when injecting cold insulin.

- A. Check the name of the pen (see **Figure B**) to make sure you have the **correct insulin** - this is especially important if you have other pens. The body and button of Ezelin are both in blue.

- B. Check the expiration date

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

- C. Pull off the cap.

- D. Check the appearance of your insulin. Ezelin is a clear insulin.

- **Do not** use your Ezelin if the insulin is cloudy, colored or contains particles.

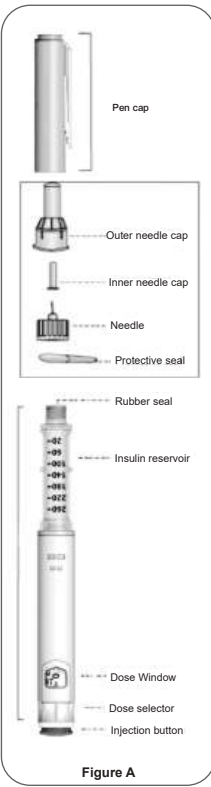


Figure A



Step 2. Attach a new needle

Do not reuse needles. Always use a new sterile needle for each injection. This helps prevent contamination and potential needle blocks.

- A. Wipe the rubber seal with an alcohol prep pad.

- B. Remove the protective seal from a new needle

- C. Screw the needle tight onto the insulin reservoir Keep it straight as you screw it on (see **Figure C**).

- If the needle is not kept straight while you attach it, it can damage the rubber seal and cause leakage, or break the needle.

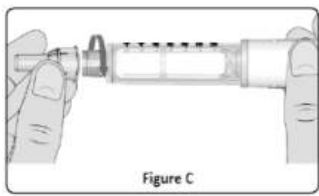


Figure C

Step 3. Perform a safety test

Always perform the safety test before each injection.

Perform the safety test to ensure you get the correct dose, by first removing air bubbles and testing that pen and needle work properly.

- A. Select a dose of 2 units by turning the dose selector clockwise (see **Figure D**).

- If necessary, the selected dose can be corrected by turning the dose selector anticlockwise.

- B. Pull off the outer needle cap (see **Figure E**) and put it aside to remove the used needle after the injection is completed.

- C. Pull off the inner needle cap and discard it.

- D. Hold the pen with the needle pointing upwards and tap the insulin reservoir so that air bubbles can rise up towards the needle (See **Figure F**).

- E. Press the injection button all the way in (see **Figure G**). Check if insulin comes out of the needle tip. Your pen is working correctly if insulin comes out of the needle. You may have to perform the safety test (repeat Step A, Step D and Step E) 1 to 3 times before insulin comes out of the needle tip.

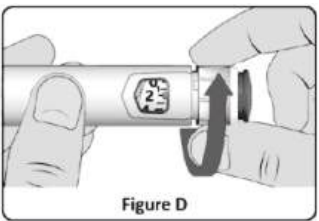


Figure D

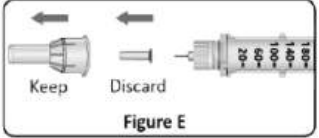


Figure E

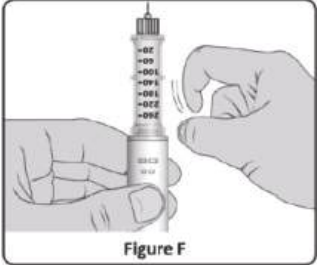


Figure F

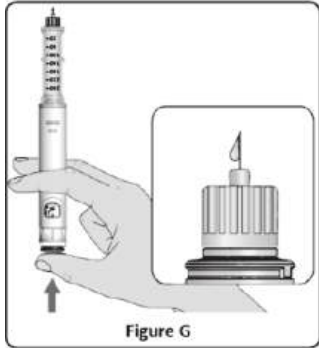


Figure G

If no insulin comes out of the needle tip :

- Check for air bubbles and repeat the safety test no more than 5 times to remove them.
- If still no insulin comes out, the needle may be blocked. Change the needle and repeat the safety test.
- If no insulin comes out after changing the needle, your GanyPen may be damaged-do not use this Ezelin.

- F. Check that the dose window shows "0" following the safety test if not, do not use this Ezelin.

Step 4. Select your dose

- A. Select your required dose by turning the dose selector (example in **Figure H**: selected dose is 30 units).

- After adjustment, it is necessary to observe whether the scale value is in the specified position. If you turn past your dose, you can turn back down.
- **Do not** push the injection button while turning, as insulin will come out.
- You cannot turn the dose selector past the number of units left in the pen.
- If the drug left in the pen is less than your dose, inject what is remaining in the pen and complete your dose with a new Ezelin, or use a new pen for your full dose. Please be aware that the new pen also requires a safety test (see Step 3).

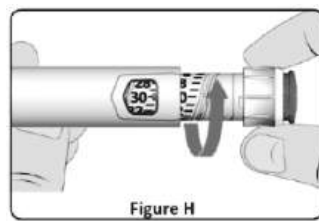


Figure H

Step 5. Inject the dose

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

- A. Choose your injection site.

- Ezelin can be injected in your thigh, stomach area (abdomen) or upper arm **Figure I**: grey areas).
- Change your injection site for each injection.
- 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 damage skin.

- B. Clean the injection site with an alcohol prep pad. Leave it to dry before injecting.

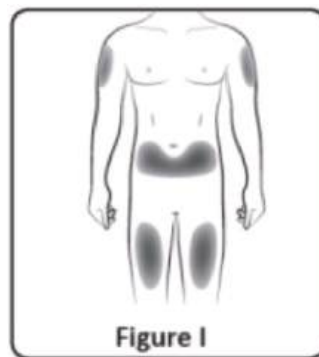


Figure I

- C. Insert the needle into the skin. (see **Figure J**).

- D. Press the injection button all the way to deliver the dose.

- The number in the dose window will return to "0" as you inject. It indicates that you have injected a sufficient dose.
- You should press the button to deliver the dose. Turning the dose selector cannot deliver the dose successfully.
 - Use the injection method recommended by your healthcare professional. Keep the injection button pressed to ensure the full dose is given.
 - You can interrupt the injection by loosening the injection button. The remaining dose can be observed in the dose window. Pressing the injection button again will continue the injection.

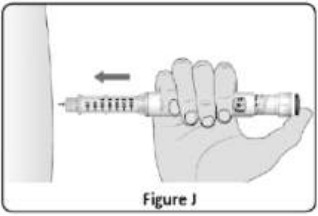


Figure J

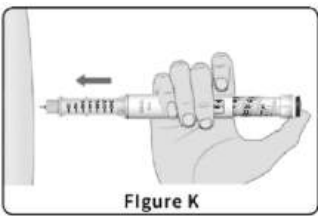


Figure K

When a large dose of insulin (such as 60U) is injected, the index finger can be released without contact between the index finger and the scale cylinder. The middle finger can be placed below the scale window and injected close to the scale window without blocking the scale (see **Figure K**) to ensure that the injection force is carried out from top to bottom.

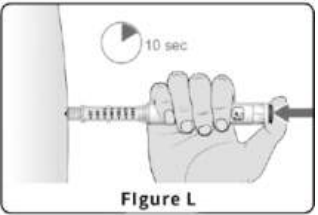


Figure L

- E. Keep the injection button pressed all the way in.

When the full dose of insulin is injected, keep holding the injection button for 10 seconds to ensure the completion of dose delivery. Slowly pull out the needle after that.

Slowly count to 10 before you withdraw the needle from the skin.(see **Figure L**).

This ensures that the full dose is delivered.

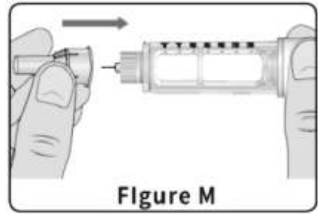


Figure M

Step 6. Remove the needle

Always remove the needle after each injection and store Ezelin without a needle attached.

- A. Carefully put the outer needle cap back on the needle (see **Figure M**) to reduce the risk of accidental needle injury. Never replace the inner needle cap.

- B. Unscrew the needle (see **Figure N**).

- C. Always put the pen cap back on. Store the pen at room temperature not above 30°C for next injection.

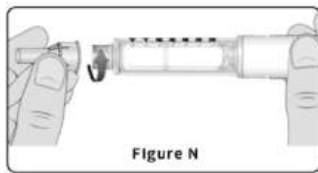


Figure N

Step 7. Dispose of the needle and pen

Dispose of the needle safely

Used needles should be placed in sharps containers (such as red biohazard containers), hard plastic containers (such as detergent bottles), or metal containers (such as empty coffee cans). Such containers should be sealed and disposed of properly.

Dispose of the empty pen

When the pen is empty, dispose of it as instructed by your healthcare professional or local authorities.

Storing Ezelin

Before first use

- Keep your Ezelin in the refrigerator between 36°F to 46°F (2°C-8°C) until first use.
- **Do not** freeze. Discard your pen if it has been frozen or crystallized.

After first use

- Store the Ezelin you are currently using at room temperature below 86°F (30°C), and away from light, dust, and dirt.
- Ezelin in use must not be stored in a refrigerator.
- You can use it for up to 28 days after your first injection. Do not use it after this time.
- **Do not** store your pen with the needle attached.
- Keep your pen out of the reach and sight of children and any other persons who are not supposed to handle it

Maintenance

- You can clean the outside of your pen by wiping it with a damp soft cloth.
- **Do not** soak, wash, or lubricate the pen as this may damage it.
- Your Ezelin should be handled with care. Avoid situations where Ezelin might be damaged. If you are concerned that your Ezelin may be damaged, use a new one.



BACK