

PATIENT INFORMATION

REZVOGLAR™ KWIKPEN® (REHZ-voh-glahr) (insulin glargine-aglr) injection for subcutaneous use, 100 Units/mL (U-100)

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.

What is REZVOGLAR?

REZVOGLAR is a long-acting man-made insulin used to control high blood sugar in adults and children with diabetes mellitus. REZVOGLAR is not for use to treat diabetic ketoacidosis.

Who should not use REZVOGLAR?

Do not use REZVOGLAR if you:

- are having an episode of low blood sugar (hypoglycemia).
- have an allergy to insulin glargine products or any of the ingredients in REZVOGLAR. See the end of this Patient Information leaflet for a complete list of ingredients in REZVOGLAR.

What should I tell my healthcare provider before using REZVOGLAR?

Before using REZVOGLAR, tell your healthcare provider about all your medical conditions including if you:

- have liver or kidney problems.
- take other medicines, especially ones called TZDs (thiazolidinediones).
- have heart failure or other heart problems. If you have heart failure, it may get worse while you take TZDs with REZVOGLAR.
- are pregnant, planning to become pregnant, or are breastfeeding. It is not known if REZVOGLAR may harm your unborn baby or breastfeeding baby.

Tell your healthcare provider about all the medicines you take including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Before you start using REZVOGLAR, talk to your healthcare provider about low blood sugar and how to manage it.

How should I use REZVOGLAR KwikPen?

- Read the detailed **Instructions for Use** that come with your REZVOGLAR KwikPen single-patient-use prefilled pen.
- Use REZVOGLAR exactly as your healthcare provider tells you to. Your healthcare provider should tell you how much REZVOGLAR to use and when to use it.
- Know the amount of REZVOGLAR you use. **Do not** change the amount of REZVOGLAR you use unless your healthcare provider tells you to.
- Check your insulin label each time you give your injection to make sure you are using the correct insulin.
- The dose indicator on your pen shows your dose of REZVOGLAR. Do not make any dose changes unless your healthcare provider tells you to.
- **Do not** use a syringe to remove REZVOGLAR from your KwikPen disposable prefilled pen.
- **Do not** re-use needles. Always use a new needle for each injection. Re-use of needles increases your risk of having blocked needles, which may cause you to get the wrong dose of REZVOGLAR. Using a new needle for each injection lowers your risk of getting an infection. If your needle is blocked, follow the instructions in **Step 3** of the **Instructions for Use**.
- You may take REZVOGLAR at any time during the day but you must take it at the same time every day.
- REZVOGLAR is injected under the skin (subcutaneously) of your upper legs (thighs), upper arms, or stomach area (abdomen).

- **Do not** use REZVOGLAR in an insulin pump or inject REZVOGLAR into your vein (intravenously).
- **Change (rotate) your injection sites within area you chose with 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.
 - o **Do not** use the exact same spot for each injection.
 - o **Do not** inject where the skin has pits, is thickened, or has lumps.
 - o **Do not** inject where skin is tender, bruised, scaly or hard, or into scars or damaged skin.
- **Do not** mix REZVOGLAR with any other type of insulin or liquid medicine.
- **Check your blood sugar levels.** Ask your healthcare provider what your blood sugar should be and when you should check your blood sugar levels.

Keep REZVOGLAR and all medicines out of the reach of children.

Your dose of REZVOGLAR may need to change because of:

- a change in level of physical activity or exercise, weight gain or loss, increased stress, illness, change in diet, or because of the medicines you take.

What should I avoid while using REZVOGLAR?

While using REZVOGLAR do not:

- drive or operate heavy machinery, until you know how REZVOGLAR affects you.
- drink alcohol or use over-the-counter medicines that contain alcohol.

What are the possible side effects of REZVOGLAR and other insulins?

REZVOGLAR may cause serious side effects that can lead to death, including:

- **low blood sugar (hypoglycemia).** Signs and symptoms that may indicate low blood sugar include:
 - o dizziness or light-headedness, sweating, confusion, headache, blurred vision, slurred speech, shakiness, fast heartbeat, anxiety, irritability or mood change, hunger.
- **severe allergic reaction (whole body reaction). Get medical help right away if you have any of these signs or symptoms of a severe allergic reaction:**
 - o a rash over your whole body, trouble breathing, a fast heartbeat, or sweating.
- **low potassium in your blood (hypokalemia).**
- **heart failure.** Taking certain diabetes pills called TZDs (thiazolidinediones) with REZVOGLAR may cause heart failure in some people. This can happen even if you have never had heart failure or heart problems before. If you already have heart failure it may get worse while you take TZDs with REZVOGLAR. Your healthcare provider should monitor you closely while you are taking TZDs with REZVOGLAR. Tell your healthcare provider if you have any new or worse symptoms of heart failure including:
 - o shortness of breath, swelling of your ankles or feet, sudden weight gain.

Treatment with TZDs and REZVOGLAR may need to be changed or stopped by your healthcare provider if you have new or worse heart failure.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, swelling of your face, tongue, or throat, sweating, extreme drowsiness, dizziness, confusion.

The most common side effects of REZVOGLAR include:

- low blood sugar (hypoglycemia), weight gain; allergic reactions, including reactions at your injection site, skin thickening or pits at the injection site (lipodystrophy).

These are not all the possible side effects of REZVOGLAR. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of REZVOGLAR.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. **Do not** use REZVOGLAR for a condition for which it was not prescribed. **Do not** give REZVOGLAR to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about REZVOGLAR. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about REZVOGLAR that is written for healthcare professionals. For more information about REZVOGLAR call 1-800-545-5979 or go to the website www.rezvoglar.com.

What are the ingredients in REZVOGLAR?

- **Active ingredient:** insulin glargine-aglr
- **3 mL KwikPen prefilled pen inactive ingredients:** glycerin, metacresol, zinc, and Water for Injection, USP.

Hydrochloric acid and/or sodium hydroxide may be added to adjust the pH.

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This Patient Information has been approved by the U.S. Food and Drug Administration.

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