Patient Information

BASAGLAR® (baz-a-glar)
(insulin glargine injection) 100 units per mL (U-100) for subcutaneous use

What is BASAGLAR?

• BASAGLAR is a long-acting man made insulin used to control high blood sugar in adults and children with type 1 diabetes mellitus and adults with type 2 diabetes mellitus.
• BASAGLAR is not for use to treat diabetic ketoacidosis.
• It is not known if BASAGLAR is safe and effective in children less than 6 years of age with type 1 diabetes mellitus or in children with type 2 diabetes mellitus.

Who should not use BASAGLAR?

Do not use BASAGLAR if you:

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

What should I tell my healthcare provider before using BASAGLAR?

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

• have liver or kidney problems.
• take any other medicines, especially ones commonly called TZDs (thiazolidinediones).
• have heart failure or other heart problems. If you have heart failure, it may get worse while you take TZDs with BASAGLAR.
• are pregnant, planning to become pregnant, or are breastfeeding. It is not known if BASAGLAR may harm your unborn 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 BASAGLAR, talk to your healthcare provider about low blood sugar and how to manage it.

How should I use BASAGLAR?

• Read the detailed Instructions for Use that come with your BASAGLAR.
• Use BASAGLAR exactly as your healthcare provider tells you to. Your healthcare provider should tell you how much BASAGLAR to use and when to use it.
• Know the amount of BASAGLAR you use. Do not change the amount of BASAGLAR 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.
• BASAGLAR may be used at any time during the day, but BASAGLAR should be used at the same time each day.
• Only use BASAGLAR that is clear and colorless. If your BASAGLAR is cloudy or slightly colored, return it to your pharmacy for a replacement.
• BASAGLAR is injected under the skin (subcutaneously) of your stomach area, buttocks, upper legs or upper arms. Do not use BASAGLAR in an insulin pump or inject BASAGLAR into your vein (intravenously).
• Change (rotate) your injection sites within the 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.
  • Do not use the exact same spot 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 damaged skin.

- Do not mix BASAGLAR with any other type of insulin.
- 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.
- Check your blood sugar levels. Ask your healthcare provider what your blood sugar should be and when you should check your blood sugar levels.
- Do not share your single-patient-use BASAGLAR® prefilled 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.

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

Your dose of BASAGLAR may need to change because of:

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

What should I avoid while using BASAGLAR?

While using BASAGLAR do not:

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

What are the possible side effects of BASAGLAR?

BASAGLAR 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:
  - 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:
  - 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 thiazolidinediones or “TZDs” with BASAGLAR 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 BASAGLAR. Your healthcare provider should monitor you closely while you are taking TZDs with BASAGLAR. Tell your healthcare provider if you have any new or worse symptoms of heart failure including:
  - shortness of breath, swelling of your ankles or feet, sudden weight gain.

Treatment with TZDs and BASAGLAR 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 BASAGLAR include:

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

These are not all the possible side effects of BASAGLAR. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 (1-800-332-1088).
General information about the safe and effective use of BASAGLAR.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use BASAGLAR for a condition for which it was not prescribed. Do not give BASAGLAR 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 BASAGLAR. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about BASAGLAR that is written for health professionals. For more information, go to www.basaglar.com or call 1-800-545-5979.

What are the ingredients in BASAGLAR?

- **Active ingredient:** insulin glargine
- **Inactive ingredients:** glycerin, metacresol, zinc, and Water for Injection, USP as inactive ingredients. Hydrochloric acid and/or sodium hydroxide may be added to adjust the pH.

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