Glaritus 100 IU/mL Solution for injection
Glaritus 100 IU/mL Solution for injection in Pre-filled Pen

Each ml contains Insulin Glargine 100IU

What is in this Leaflet

What Glaritus used for

The treatment of type 1 or type 2 diabetes mellitus patients who require insulin for the control of hyperglycaemia.

How Glaritus works

After injection into the subcutaneous tissue, te acidic solution is neutralised,leading to formation of microprecipptates from which small amounts of insulin glargine are continuously released, providing a smooth,peakles,predictable time/concentration profile and a prolonged duration of action.
This allows once daily dosing to meet a patient's basal insulin needs.

Before you use Glaritus

When you must not use it

Inform your doctor if you have any problem listed below, as the doctor will decide whether you should be started on Glaritus

- If you have diabetic ketoacidosis
- In patients with renal impairment, insulin requirements may be diminished
- In patients with severe hepatic impairment, insulin requirements may be diminished due to reduced capacity for gluconeogenesis and reduced insulin metabolism.

Before you start to use it

Insulin glargine must not be used in patients hypersensitive to insulin glargine or any of its excipients.

Taking other medicines

A number of substances affect glucose metabolism and may require insulin dose adjustment.
Substances that may enhance the blood glucose lowering effect and susceptibility to hypoglycaemia include:

-oral antidiabetic agents, ACE inhibitors, Pentoxifylline,perhexiline,disopyramide,fibrates,fluoxetine,MOA inhibitors, dextropropoxyphene,salicylates, sulfonamide antibiotics.

-Substances that may reduce the blood glucose lowering affect and susceptibility to hyperglycaemia include:corticosteroids,danazol,diazoxide,diuretics, Glucagon,isoniazid, oral contraceptives,phenothiazine derivatives,somatotrophin,sympathomimetic agents(e.g.epinephrine[adrenaline], salbutamol,Terbutaline),thyroid hormones, protease inhibitors and atypical antipsychotic medication(e.g. olanzapine and clozapine).

-Beta blokers,clonidine,lithium salts or alcohol may either potentiate or weaken the blood glucose lowering effect of insulin.

-Pentamidine may cause Hypoglycaemia, which may be sometimes be followed by hyperglycaemia.

-In addition, under the influence of sympatholytic medicinal products such as beta-blockers,clonidine,guanethidine and reserpine,the signs of adrenergic Counter-regulation may be reduced or absent.

How to use Glaritus

How much to use

Insulin glargine is given subcutaneously once a day. The average range of total daily insulin requirement for maintenance in type 1 diabetic patients ranges between 0.5 and 1.0IU/kg.Futher in insulin resistance, the daily requirement of insulin may be substantially higher. In patients with type 2 diabetes, the requirements of insulin are lower i.e. approximately 0.3-0.6 IU/kg.Futher in insulin resistance, the daily requirement of insulin may be substantially higher. In patients with type 2 diabetes, the requirements of insulin are lower i.e. approximately 0.3-0.6IU/kg/day. Dose adjustment may be required, if patients undertake increased physical activity or change their usual diet or if the patients weight or lifestyle change or other circumstances arise that increase susceptibility to hypo or hyperglycaemia.Any change of insulin dose should be made cautiously and only under medical supervision.

When to use it

Insulin glargine is given subcutaneously once a day. It may be administered at any time during the day,however,at the same time every day

How long to use it

It may be administered at any time during the day,however,at the same time every day. It is not intended for intravenous administration. The desired blood glucose levels as well as the doses and timing of insulin glargine, must be determined and adjusted individually by the physician.

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If you forget to use it

Take the missed dose as soon as possible as you remember it. However if it is almost for the next dose ,skip the missed dose and continue your regular schedule. Do not take a double dose to make up for a missed one.

If you use too much (overdose)

An excess of Insulin relative to food intake, energy expenditure or both may lead to severe and sometimes long-term and life-threatening hypoglycaemia.

Mild episodes of hypoglycaemia can usually be treated with oral glucose/carbohydrates. Adjustments in drug dosage, meal pattern, or exercise may be
Needed.

More severe episodes with coma, seizure or neurologic impairment may be treated with intramuscular/subcutaneous glucagon or concentrated intravenous Glucose.

After apparent clinical recovery from hypoglycaemia, continued, observation and additional carbohydrate intake may be necessary to avoid recurrence
of hypoglycaemia.

It is therefore recommended that the diabetic patient constantly carry some sugar lumps,sweets,biscuits,or sugary fruit juice. Adjustments in drug dosage,
Meal patterns, or exercise, may be needed.

Get medical help as soon as possible if any of the above symptoms is observed.

While you are using it

Things you must do

Follow doctor's advice.

Things you must not do

Do not stop taking without consulting doctor first.
Do not give your medicine to whom experiencing the same symptoms as you.

Things to be careful of

-Intercurrent Conditions

Insulin requirements may be altered during intercurrent condition such as illness, emotional disturbances or stress.

-Use in pregnancy

To date, no relevant epidemiological data are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal

or foetal development, parturition or postnatal development.

It is essential for patients with pre-existing or gestational diabetes to maintain good metabolic control throughout pregnancy. Insulin requirement may

Decrease during the first trimester, increase during the second and third trimesters and rapidly decline after delivery. Careful blood glucose control is essential

-In such patients. Effects on the ability to drive and use machines:

-The patient's ability to concentrate and react may be impaired as a result of hypoglycemia. This may constitute a risk in situations where these abilities are of special importance (e.g. driving a car or operating machinery).This is particularly significant in patients who have reduced awareness of the

-Warning signs of hypoglycemia or have frequent episodes of hypoglycemia.

Side Effects

Hypoglycemia, Oedema, Hyperglycemia and Ketoacidosis,redness,swelling,and itching at the site of injection,

Visit your doctor or pharmacist immediately if you experience any side effects even if they are not listed here, after taking this medicine.

You may reportany side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: ***03-78835490,*** *or visiting the website*

npra.gov.my*[Consumers →Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]*

Storage and Disposal of Glaritus

Storage

Storage +2°C to +8°C, protect from light. Do not freeze.Keep out of reach of children.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

Glaritus 100 IU/mL Solution for injection : Strerile solution in a 3ml catridge

Glaritus 100 IU/mL Solution for injection in Pre-filled Pen :
Strerile solution in a 3ml catridge fitted in a Pre-filled Pen

Ingredients:

Active Ingredient
Insulin Glargine

Inactive ingredients
Zinc Chloride,Glycerol(85%),m-Cresol,Hydrochloric Acid,Sodium Hydroxide and water for Injection.

MAL No.**:**

Manufactured and Released by:

Wockhardt Limited
Biotech Park,H-14/2,M.I.D.C,Waluj, Aurangabad-431 136,Maharashtra, INDIA.

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Product Registration Holder
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NPRA (R3) 19/003

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