

Glarine®

Insulin Glargine (rDNA) USP Sterile injection

Description

Glarine® (Insulin glargine [rDNA] injection) is a sterile solution of insulin glargine for use as a subcutaneous injection. Insulin glargine is a recombinant human insulin analog that is a long-acting (up to 24-hour duration of action), parenteral blood-glucose-lowering agent. **Glarine®** is produced by recombinant DNA technology utilizing a non-pathogenic laboratory strain of Escherichia coli (K12) as the production organism. It is a recombinant human insulin analog that is long acting (up to 24 hour duration of action), parenteral blood glucose lowering agent.

Primary function of insulin, including insulin glargine, is regulation of glucose metabolism. Insulin and its analogs lower blood glucose by stimulating peripheral glucose uptake, primarily by skeletal muscle and fat, and by inhibiting hepatic glucose production. Insulin inhibits lipolysis and proteolysis, and enhances protein synthesis.

Indications

Glarine® is indicated to improve glycemic control in adults and children with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.

Procedure for Insulin Administration

Before going for administration of **Glarine®** please follow the below mentioned check list:

1. Insulin syringe of the right size (100 IU)
2. Prescribed type of insulin injection
3. Check the expiry date on **Glarine®** vial
4. Ensure that the flip-off cap on the **Glarine®** vial is intact

After that follow the below mentioned instructions as per given picture:



1. Wash your hands carefully. Shake or roll **Glarine®** vial 10 times to completely mix the insulin.



2. Inspect the vial. **Glarine®** should appear as clear colorless solution.



3. When using a new vial, flip off the plastic protective cap, but do not remove the stopper. The tip of the vial should be wiped an alcohol swab.



6. Turn the bottle and syringe upside down. Hold the bottle and syringe firmly in one hand and shake gently. Make sure that the tip of the needle is in the liquid; withdraw the correct dose of insulin into the syringe.

7. Before removing the needle from the vial, check the insulin syringe for air bubbles, which reduces the amount of insulin in it, if bubbles are present, hold the insulin straight up and tap its side until the bubbles float to the top. Push them out with the plunger and withdraw

8. Lightly pinch up the skin, holding the syringe like a pencil.



4. Draw air in to the syringe equal to your insulin dose.



9. Insert the needle in to the skin & push the plunger slowly. Make sure that the needle is all the way in.



5. Insert needle in to vial through rubber top & push plunger to empty the air in to the vial.



10. Wait for 5 seconds & pull out the syringe. Do not rub the area.

Dosage

Glarine[®] exhibits a relatively constant glucose-lowering profile over 24 hours that permits once-daily dosing. Potency of insulin glargine is approximately the same as human insulin.

Glarine[®] is recommended for once daily subcutaneous administration & may be administered at any time during the day. However, once started should be administered at the same time every day. The dose of **Glarine**[®] must be individualized based on clinical response. Blood glucose monitoring is essential in all patients with diabetes. In patients with type 1 diabetes, **Glarine**[®] must be used in regimens with short-acting insulin. **Glarine**[®] is not recommended for intravenous administration. Intravenous administration of the usual subcutaneous dose could result in severe hypoglycemia.

Injection sites should be rotated within the same region (abdomen, thigh, or deltoid) from one injection to the next.

Initiation of **Glarine**[®] therapy:

The recommended starting dose of **Glarine**[®] in patients with type 1 diabetes should be approximately one-third of the total daily insulin requirements. Short-acting, premeal insulin should be used to satisfy the remainder of the daily insulin requirements.

The recommended starting dose of **Glarine**[®] in patients with type 2 diabetes who are not currently treated with insulin is 10 units (or 0.2 Units/kg) once daily, which should subsequently be adjusted to the patient's needs.

Converting to **Glarine**[®] from other insulin therapies

If changing from a treatment regimen with an intermediate- or long-acting insulin to a regimen with **Glarine**[®], the amount and timing of shorter-acting insulins and doses of any oral anti-diabetic drugs may need to be adjusted.

- If transferring patients from once-daily NPH insulin to once-daily **Glarine**[®], the recommended initial **Glarine**[®] dose is the same as the dose of NPH that is being discontinued.

- If transferring patients from twice-daily NPH insulin to once-daily **Glarine**[®], the recommended initial **Glarine**[®] dose is 80% of the total NPH dose that is being discontinued.

Pregnancy & lactation

Pregnancy: Pregnancy category C. Insulin glargine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: It is unknown whether insulin glargine is excreted in human milk. Because many drugs, including human insulin, are excreted in human milk, caution should be exercised when Insulin glargine is administered to a nursing woman. Lactating women may require adjustments in insulin dose & diet.

Side Effects

Side effects of Insulin glargine are hypoglycemia, allergic reactions, injection site reaction, lipodystrophy, pruritus, and rash.

Contraindications

Insulin glargine is contraindicated in patients with hypersensitivity to Insulin glargine or one of its excipients.

Precautions

Dose adjustment and monitoring: Blood glucose should be monitored in all patients treated with insulin. Insulin regimens should be modified cautiously and only under medical supervision.

Administration: Insulin glargine must not be diluted or mixed with any other insulin or solution. It should not be administered subcutaneously via an insulin pump or intravenously because severe hypoglycemia can occur.

Renal or hepatic impairment: Reduction in the Insulin glargine dose may require in these cases.

Drug Interactions

A number of drugs affect glucose metabolism and may require dose adjustment. The following substances may reduce the Insulin as well as Insulin glargine requirements: oral anti-diabetic products, angiotensin converting enzyme (ACE) inhibitors, disopyramide, fibrates, fluoxetine, monoamine oxidase inhibitors, propoxyphene, pentoxifylline, salicylates and sulfonamide antibiotics.

The following substances may increase the Insulin as well as Insulin glargine requirements: Thiazides, glucocorticoids, thyroid hormones, beta-sympathomimetic, growth hormone and danazol.

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

Over dosage

Insulin glargine overdose may result in hypoglycemia. Mild episodes of hypoglycemia can usually be treated with oral carbohydrates. Severe hypoglycemia may be treated with parenteral glucose or injections of glucagon. Adjustments in drug dosage, meal patterns, or exercise may be needed.

Pharmaceutical precautions/Storage

Store at 2° C to 8° C in a refrigerator. Do not freeze. Protect from light.

Presentation

Glarine[®] Injection 100 IU/ml: Each ml solution contains Insulin Glargine (rDNA) INN 100 IU (equivalent to 3.47 mg).

Commercial Pack

Glarine[®] Injection 100 IU/ml: Each box contains 3 ml solution in glass vial.

® Registered Trade Mark



ACI Limited