

Larsulin™

Insulin Glargine (rDNA)

Composition

Larsulin™ Injection: Each ml solution contains Insulin Glargine (rDNA) INN 100 IU.

Larsulin™ Pen Cartridge: Each ml solution contains Insulin Glargine (rDNA) INN 100 IU.

Description

Larsulin™ is a sterile solution of insulin glargine for use as a subcutaneous injection. Insulin glargine is a recombinant human insulin analogue that is a long-acting (up to 24-hour duration of action), parenteral blood glucose lowering agent. **Larsulin™** is produced by recombinant DNA technology.

Primary function of insulin glargine is regulation of glucose metabolism. Insulin and its analogues lower blood glucose by stimulation 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

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

USAGE

1. **Larsulin™** should be injected subcutaneously once daily at any time of day, but at the same time everyday.

2. *Prepare before use*

Cartridge: According to the instruction of **AnsuPen®**, insert the **Larsulin™** cartridge into the pen correctly and equip the needle. Gently turn the pen upside down for 8-10 times until the insulin in the cartridge becomes uniformly mixed.

Adjust the dosage button to get correct dose. After removal of the needle cap and discharge air bubbles in the cartridge, it is ready to be injected. In order to avoid cross contamination, do not let the needle touch anything during the process of preparation.

Vial:

- Firstly, clean your hands. Shake or rotate the vial gently to mix the solution uniformly and check if the insulin has the normal appearance.
- If using a new **Larsulin™** bottle then flip off the plastic protective cap and wipe the rubber stopper with an alcohol swab.
- Draw air into your syringe equal to the amount of **Larsulin™** needed. Puncture the needle into the vial and inject the air.
- Turn the bottle and syringe upside down. Withdraw correct dose of **Larsulin™** into the syringe. Before pulling out the needle, check if there are any bubbles remain in the syringe.

If so, put the syringe upright and tap the syringe to discharge the air bubbles.

3. Injection Site

Choose the area where skin is less tight, such as the upper arm, thigh, buttock and abdomen, etc. To avoid tissue damage, choose a site for each injection that is at least 1 cm from the previous injection site.

4. Injection Method

Cleanse the skin with alcohol where the injection is to be made. Put the needle in such a position as to form 45° angle with the skin. Puncture the needle into skin and inject insulin. Then pull the needle out and apply gentle pressure over the injected site for several seconds. Do not rub the injection site.

Dosage & Administration

Larsulin™ 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.

Larsulin™ 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 **Larsulin™** must be individualized based on clinical response. Blood glucose monitoring is essential in all patients with diabetes. In patients with type 1 diabetes, **Larsulin™** must be used in regimens with short-acting insulin. **Larsulin™** is not recommended for intravenous administration. Intravenous administration of the usual subcutaneous dose could result in severe hypoglycemia.

Initiation of **Larsulin™** therapy:

The recommended starting dose of **Larsulin™** 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 **Larsulin™** 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 **Larsulin™** from other insulin therapies

If changing from a treatment regimen with an intermediate- or long-acting insulin to a regimen with **Larsulin™**, 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 **Larsulin™**, the recommended initial **Larsulin™** dose is the same as the dose of NPH that is being discontinued.
- If transferring patients from twice-daily NPH insulin to once-daily **Larsulin™**, the recommended initial **Larsulin™** dose is 80% of the total NPH dose that is being discontinued.

Side Effects

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

Use in 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.

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.

Contraindications

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

Drug Interaction

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-sympathomimetics, growth hormone and danazol.

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

Overdose

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.

Storage

Store at 2° C to 8° C in a refrigerator. Do not freeze. In case of insulin for recent use need not to be refrigerated, try to keep it in a cool place and keep away from heat and light. The insulin in use can be kept under the room temperature for a month.

How Supplied

Larsulin™ Injection: Each vial contains 3 ml solution.

Larsulin™ Pen Cartridge: Each cartridge contains 3 ml solution.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.

Kaliakoir, Bangladesh

TM- Trade Mark

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