For the use only of a Registered Medical Practitioner or Hospital or a Laboratory

Abridged Prescribing Information

INSULIN GLARGINE INJECTION I.P. (r-DNA origin)
LANTUS® 100 IU/mL

COMPOSITION
1 mL contains 3.6378 mg insulin glargine I.P, corresponding to 100 IU human insulin.
Each cartridge and pre-filled disposable pen (SoloStar®) contains 3 ml, equivalent to 300 IU insulin. Each vial contains 10 ml equivalent to 1000 IU.

INDICATION
For the treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.

DOSAGE AND ADMINISTRATION
Lantus® should be administered subcutaneously once daily at any time but at the same time each day. The dosage and timing of dose of Lantus® should be individually adjusted. In patients with type 2 diabetes mellitus, Lantus® can also be given together with orally active antidiabetic products. When changing from a treatment regimen with an intermediate or long-acting insulin to a regimen with Lantus®, the amount and timing of short acting insulin or fast acting insulin analogue or of the dose of any oral antidiabetic drug may need to be adjusted. Close metabolic monitoring is recommended. Lantus® is administered subcutaneously, should not be administered intravenously and must not be mixed with any other insulin or diluted. Lantus® is not the insulin of choice for the treatment of diabetic ketoacidosis.
To reduce the risk of hypoglycemia, when patients are transferred from once daily insulin glargine 300U/mL to once daily Lantus®, the recommended initial Lantus® dose is 80% of the insulin glargine 300U/mL dose that is being discontinued.

SAFETY-RELATED INFORMATION
Contraindications: Hypersensitivity to insulin glargine or to any of the excipients.

Precautions: Insulin treatment requires constant alertness to the possibility of hyper and hypoglycemia. Patients and their relatives must know what steps to take if hyperglycaemia or hypoglycemia occurs or is suspected, and they must know when to inform a physician. Continuous rotation of the injection site must be performed to reduce the risk of developing lipodystrophy and localized cutaneous amyloidosis. potential risk of delayed insulin absorption and worsened glycemic control following insulin injections at sites with these reactions. A sudden change in the injection site to an unaffected area has been reported to result in hypoglycemia. Blood glucose monitoring is recommended after the change in the injection site, and dose adjustment of antidiabetic medications may be considered. Hypoglycemia may occur. The time of occurrence of hypoglycaemia depends on the action profile of the insulins used and may, therefore, change when the treatment regimen is changed. As with all insulins, particular caution should be exercised, and intensified blood glucose monitoring is advisable, in patients in whom sequelae of hypoglycemic episodes might be of particular clinical relevance. In patients with renal impairment or severe hepatic impairment, insulin requirements may be diminished due to reduced insulin metabolism. In the elderly, progressive deterioration of renal function may lead to a steady decrease in insulin requirements. Hypoglycemia can generally be corrected by immediate carbohydrate intake. So that initial corrective action can be taken immediately, patients must carry a minimum of 20 grams of carbohydrates with them at all times. Intercurrent illness requires intensified metabolic monitoring. In many cases urine tests for ketones are indicated, and often it is necessary to adjust the insulin dose. Lantus® cartridges should be used with Allstar® and not with any other reusable pen as dosing accuracy has only been established with the above listed pens.

Pregnancy& Lactation: There are no randomized controlled clinical studies on the use of insulin glargine in pregnant women. A large number (more than 1000 retrospective and prospective pregnancy outcomes) of exposed pregnancies from Post Marketing Surveillance indicate no specific adverse effects of insulin glargine on pregnancy or on the health of the foetus and newborn child. Lantus® can be used during pregnancy, if clinically needed. Insulin requirements may decrease during the first trimester and generally increase during the second and third trimesters. Immediately after delivery, insulin requirements decline rapidly. Careful monitoring of glucose control is essential in such patients. Patients with diabetes must inform their doctor if they are pregnant or are contemplating pregnancy.

Adverse Reactions: Most frequent: Hypoglycemia may occur if the insulin dose is too high in relation to the insulin requirement, temporary visual impairment may occur. Lipodystrophy may occur at the injection site. Injection site reactions including redness, pain, itching, hives, swelling or inflammation. Localized cutaneous amyloidosis at the injection site has occurred with insulins. Hyperglycemia has been reported with repeated insulin injections into areas of localized cutaneous amyloidosis and hypoglycemia with a sudden change to an unaffected injection site

For full prescribing information, refer to the company website www.sanofi.in

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