LANTUS® Abbreviated Prescribing Information

1. **NAME AND PRESENTATION:** Lantus SoloStar 100 units/ml solution for injection in a pre-filled pen. Disposable pens (Solostar®) (3 ml) contain 3.64 mg of insulin glargine per ml corresponding to 100 IU human insulin/ml.

2. **THERAPEUTIC INDICATIONS: T**reatment of diabetes mellitus in adults, adolescents, and children of 2 years and above.

3. **POSOLOGY AND METHOD OF ADMINISTRATION:** Lantus contains insulin glargine, an insulin analogue, and has a prolonged duration of action. Lantus should be administered once daily at any time but at the same time each day. The dose regimen (dose and timing 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 intermediate or long-acting insulin to a regimen with Lantus, a change of the dose of the basal insulin may be required and the concomitant antidiabetic treatment may need to be adjusted. Close metabolic monitoring is recommended. Administration: Lantus is administered subcutaneously, should not be administered intravenously, and must not be mixed with any other insulin or diluted.

4. **CONTRA-INDICATIONS:** Hypersensitivity to insulin glargine or to any of the excipients listed in full Smpc

5. **SPECIAL WARNINGS AND PRECAUTIONS FOR USE:** Lantus is not the insulin of choice for the treatment of diabetic ketoacidosis. In patients with renal impairment, insulin requirements may be diminished due to reduced insulin metabolism. In patients with hepatic impairment, insulin requirements may be diminished due to reduced capacity for gluconeogenesis and reduced insulin metabolism. In the elderly, progressive deterioration of renal function may lead to a steady decrease in insulin requirements. Particular caution should be exercised, and intensified blood glucose monitoring is advisable in patients in whom hypoglycemic episodes might be of particular clinical relevance, such as in patients with significant stenosis of the coronary arteries or of the blood vessels supplying the brain (risk of cardiac or cerebral complications of hypoglycemia) as well as in patients with proliferative retinopathy, particularly if not treated with photocoagulation (risk of transient amaurosis following hypoglycemia). The warnings symptoms of hypoglycemia may be changed less pronounced or absent in certain risk groups.

6. **DRUG INTERACTIONS:** Substances that may increase susceptibility to hypoglycemia or reduce the blood-glucose-lowering effect are detailed in the full SmPC.

7. **PREGNANCY AND LACTATION:** No clinical data on exposed pregnancies from controlled clinical studies are available. A large amount of data on pregnant women (more than 1000 pregnancy outcomes) indicate no specific adverse effects of insulin glargine on pregnancy and no specific malformative nor feto/neonatal toxicity of insulin glargine, The use of Lantus may be considered during pregnancy, if clinically needed. Lactating women may require adjustments in insulin dose & diet.

8. **EFFECTS ON ABILITY TO DRIVE:** Patients should be advised to take precautions to avoid hypoglycemia whilst driving.

9. **UNDESIRABLE EFFECTS:** Hypoglycemia may occur if the insulin dose is too high in relation to the insulin requirement. Lipodystrophy may occur at the injection site. Injection site reactions include redness, pain, itching, hives, swelling, or inflammation. For rare adverse events, please refer to the full SmPC.

10. **OVERDOSAGE:** may lead to severe and sometimes long-term and life-threatening hypoglycemia. Mild episodes of hypoglycemia can usually be treated with oral carbohydrates.

11. **STORAGE:**

- Not in use Pens (Solostar): Store in a refrigerator (2°c - 8°c), do not freeze or place next to freezer compartment or freezer pack. Keep the prefilled pens in the outer carton in order to protect them from light.
- In use Pens (Solostar): The medicinal product may be stored for a maximum 28 days (4 weeks) not above 30° C, and away from direct heat or direct light. Pens in use must not be stored in the refrigerator. Pen cap must be put back on the pen after each injection in order to protect from light

12. **Shelf-life:** 3 years.

13. **PHARMACOLOGICAL PROPERTIES:** ATC Code: A10AE04.

14. **MARKETING AUTHORIZATION HOLDER:** Sanofi-Aventis Deutschland GmbH,

D-65926 Frankfurt am Main, Germany

15. **Revision text date August 2020**

To report an adverse event or if you have any medical enquiry, please call +962 6 55 63 6 60 or email us at:

Levant.medinfo@sanofi.com for medical enquiries,
Quality.Levant@sanofi.com for product technical complaints,
For adverse events: Levant.Pharmacovigilance@sanofi.com

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