LANTUS ® Abridged Prescribing Information:

1. NAME & PRESENTATION: Lantus 100 U/ml, solution for injection of insulin glargine is available in a vial of 10 ml and prefilled disposable pens of 3 ml for Lantus Solostar.

2. Therapeutic INDICATIONS: Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.

3. DOSAGE & Posology OF ADMINISTRATION: Lantus is given subcutaneously once a day. It may be administered at any time during the day, however, at the same time every day. The dosage and timing of dose should be adjusted individually. In patients with type 2 diabetes mellitus, Lantus can also be given together with orally active antidiabetic agents. Lantus is not the insulin of choice for the treatment of diabetic ketoacidosis. To reduce the risk of hypoglycaemia, when patients are transferred from once daily insulin glargine 300 Units/mL to once daily Lantus, the recommended initial Lantus dose is 80% of the insulin glargine 300 Units/mL dose that is being discontinued. When changing from a treatment regimen with an intermediate or long-acting insulin to a regimen with Lantus, a change of the dose and timing of the basal insulin may be required, and the concomitant antidiabetic treatment may need to be adjusted.

4. SPECIAL POPULATION - Children: Lantus can be administrated to children ≥ 2 year of age. **Elderly:** It is recommended that the initial dosing, dose increments, and maintenance dosage be conservative to avoid hypoglycemia.

4. CONTRA-INDICATIONS: Hypersensitivity to the active substance or to any of the excipients.

5. WARNINGS & PRECAUTIONS - General: Patient should be instructed on glucose monitoring, proper injection technique and management of hypo/hyperglycemia. **Hypoglycemia:** Particular caution should be exercised, and intensified blood glucose monitoring is advisable, in patients in whom sequel of hypoglycaemic episodes might be of particular clinical relevance. In patients with renal and/or hepatic impairment, insulin requirement may be diminished due to reduced insulin metabolism or reduced capacity for gluconeogenesis. **Intercurrent illness**: These require intensified metabolic monitoring and insulin requirement may increase.

6. INTERACTIONS: Substances that may enhance or reduce the blood glucose lowering effect and susceptibility to hypoglycemia are detailed in the full prescribing information.

7. PREGNANCY AND LACTATION: No clinical data from clinical trials are available. Large amount of data on pregnant women are available (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. Lantus can be used during pregnancy, if clinically needed. Insulin requirements may decrease during the first trimester and 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. Lactating women may require adjustments in insulin dose and diet.

8. EFFECTS ON ABILITY TO DRIVE: The patient's ability to concentrate and react may be impaired as a result of, for example, hypoglycemia or hyperglycemia or, for example, as a result of visual impairment.

9. ADVERSE REACTIONS: 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 including redness, pain, itching, hives, swelling, or inflammation. A marked change in glycemic control may cause temporary visual impairment. Injection site reactions were observed in 3 to 4 % of patients, such reactions include redness, pain, itching, hives, swelling, and inflammation. Also, abrupt improvement in glycemic control may be associated with temporary worsening of diabetic retinopathy. Insulin administration may cause insulin antibodies to form which may necessitate adjustment of the insulin dose in order to correct a tendency to hyper/hypoglycemia. **10. OVERDOSAGE**: Mild episodes of hypoglycemia can usually be treated with oral carbohydrates. More severe episodes may be treated with intramuscular/subcutaneous glucagon or concentrated intravenous glucose. **11. STORAGE:** Unopened vial / pen should be stored between 36–46°F and protected from sunlight. Opened 10 ml vial must be discarded within 28 days of first use. Opened Lantus SoloStar Pen must **not** be put in the refrigerator and can be used up to 28 days.

10.Overdose: Symptoms Insulin overdose may lead to severe and sometimes long-term and life-threatening hypoglycaemia.

11.Management Mild episodes of hypoglycaemia can usually be treated with oral carbohydrates. Adjustments in dose of the medicinal product, meal patterns, or physical activity may be needed. More severe episodes with coma, seizure, or neurologic

impairment may be treated with intramuscular/subcutaneous glucagon or concentrated intravenous glucose. Sustained carbohydrate intake and observation may be necessary because hypoglycaemia may recur after apparent clinical recovery.

12.Pharmacodynamics: Insulin glargine is a human insulin analogue designed to have a low solubility at neutral pH. It is completely soluble at the acidic pH of the Lantus injection solution (pH 4). After injection into the subcutaneous tissue, the acidic solution is neutralised leading to formation of micro-precipitates from which small amounts of insulin glargine are continuously released, providing a smooth, peakless, predictable concentration/time profile with a prolonged duration of action. Insulin glargine is metabolised into 2 active metabolites M1 and M2

13. MARKETING AUTHORIZATION HOLDER: Sanofi-aventis Deutschland GmbH, D - 65926 Frankfurt am Main. Abbreviated Prescribing Information based on the EU SmPC as of August 2020. Always refer to the full Summary of Product Characteristics (SmPC) before prescribing.