

Prescribing Information: Lantus® (insulin glargine) 100 units/ml solution for injection

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

Presentations: Lantus 100 units/ml solution for injection in a vial or in a cartridge. Lantus SoloStar 100 units/ml solution for injection in a pre-filled pen. Lantus cartridges and Solostar pre-filled pens each contain 3 ml of solution for injection, equivalent to 300 units insulin glargine. Each vial contains 10 ml of solution for injection, equivalent to 1000 units.

Indications: Treatment of diabetes mellitus in adults, adolescents and children of 2 years or above.

Dosage and administration: Lantus is administered subcutaneously once daily, at any time but at the same time each day. Injection sites must be rotated within a given injection area from one injection to the next in order to reduce the risk of lipodystrophy and cutaneous amyloidosis. Do not administer intravenously. Lantus dosage should be individually adjusted. In type 2 diabetes mellitus, Lantus can also be used in combination with orally active antidiabetic medicinal products. Lantus must not be mixed with other insulins or diluted.

Switch from twice daily NPH insulin to Lantus: To reduce the risk of nocturnal and early morning hypoglycaemia, patients who are changing their basal insulin regimen from a twice daily NPH insulin to a once daily regimen with Lantus should reduce their daily dose of basal insulin by 20-30% during the first weeks of treatment.

Switch from Toujeo (insulin glargine) 300 units/ml to Lantus: Lantus and Toujeo are not bioequivalent and are not directly interchangeable. To reduce the risk of hypoglycemia, patients who are changing their basal insulin regimen from an insulin regimen with once daily Toujeo to a once daily regimen with Lantus should reduce their dose by approximately 20%.

Switching from other insulins to Lantus: When switching from a treatment regimen with an 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 (dose and timing of additional regular insulins or fast-acting insulin analogues or the dose of oral antidiabetic medicinal products). Close metabolic monitoring is recommended during, and for a period after, transition from other insulins to Lantus. Dose adjustments may also be required if the patient's weight or lifestyle changes, the timing of insulin dose is changed or other circumstances arise that increase susceptibility to hypo- or hyperglycaemia. **Elderly population (≥65 years old), patients with renal or hepatic impairment:** Insulin requirements may be diminished. **Children (<2 years of age):** No data are available.

Contraindications: Hypersensitivity to insulin glargine or any excipients.

Precautions and warnings: **Traceability:** In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. Lantus is not the insulin of choice for treatment of diabetic ketoacidosis. In case of insufficient glucose control or a tendency to hypo/hyperglycaemic episodes all relevant factors must be reviewed before dose adjustment is considered. Transferring a patient to another type or brand of insulin should be done under strict medical supervision. Patients must be instructed to perform continuous rotation of the injection site to reduce the risk of developing lipodystrophy and cutaneous amyloidosis. There is a potential risk of delayed insulin absorption and worsened glycaemic 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 hypoglycaemia. Blood glucose monitoring is recommended after the change in the injection site, and dose adjustment of

antidiabetic medications may be considered. **Hypoglycaemia:** Particular caution should be exercised, and intensified blood monitoring is advisable for patients in whom hypoglycaemic episodes might be of clinical relevance and in those where dose adjustments may be required. Warning signs of hypoglycaemia may be changed, less pronounced or absent in certain risk groups. The prolonged effect of subcutaneous Lantus may delay recovery from hypoglycaemia. Due to more sustained basal insulin supply with Lantus, less nocturnal but earlier morning hypoglycaemia can be expected. **Intercurrent illness:** requires intensified metabolic monitoring. **Insulin antibodies:** administration may cause insulin antibodies to form. Rarely, this may necessitate dose adjustment. **Pioglitazone:** Cases of cardiac failure have been reported, especially in patients with risk factors for development of cardiac heart failure. Patients on this combination should be observed and pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs. **Medication errors:** Insulin labels must always be checked before each injection to avoid errors between Lantus and other insulins. Lantus SoloStar is only suitable for subcutaneous injections from its pre-filled pen. Lantus cartridges are only suitable for subcutaneous injections from a reusable pen (JuniorSTAR which delivers Lantus in 0.5 unit dose increments and Autopen 24, AllStar and AllStar PRO which all deliver Lantus in 1 unit dose increments). If administration by syringe is necessary, a vial should be used. **Interactions:** A number of substances affect glucose metabolism and may require dose adjustment of Lantus. **Pregnancy and lactation:** No clinical data on exposed pregnancies from controlled clinical trials are available. A large amount of post-marketing data indicates no specific adverse effects of Lantus in pregnancy. Use of Lantus in pregnancy can be considered 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 (increased risk of hypoglycaemia). Careful monitoring of glucose control is essential. It is unknown if Lantus is excreted in breast milk.

Adverse reactions: **Very common (≥1/10):** Hypoglycaemia. Prolonged or severe hypoglycaemia may be life-threatening. **Common (≥1/100 to <1/10):** Lipohypertrophy, injection site reactions. **Uncommon (≥1/1,000 to <1/100):** Lipoatrophy. **Rare (≥1/10,000 to <1/1,000):** Allergic reactions, visual impairment, retinopathy and oedema. **Very rare (<1/10,000):** Dysgeusia, myalgia. Overdose may lead to severe and sometimes long-term and life-threatening hypoglycaemia. **Not known:** Cutaneous amyloidosis. **Please consult SmPC for full details of the adverse reactions.**

NHS list price: 1 x 10ml Lantus vial: £25.69; 5 x 3ml Lantus cartridge: £34.75; 5 x 3ml Lantus SoloStar: £34.75.

Legal category: POM.

Marketing Authorisation (MA) holder – NI: Sanofi Aventis Deutschland GmbH, D-65926 Frankfurt am Main, Germany.

MA Numbers – NI: Vial: EU/1/00/134/012, Cartridge: EU/1/00/134/006, SoloStar: EU/1/00/134/033.

Marketing Authorisation (MA) holder – GB: Aventis Pharma Ltd, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. **MA numbers – GB:** Vial: PLGB 04425/0814; Cartridge: PLGB 04425/0815; SoloStar: PLGB 04425/0816

For more information please contact: Medical Information, Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. uk-medicalinformation@sanofi.com.

Date of preparation: July 2021. MAT-GB-2103029 (V1.0)

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to Sanofi Tel: 0800 090 2314. Alternatively, send via email to UK-drugsafety@sanofi.com