Prescribing Information

Lantus® (insulin glargine). Please refer to Summary of Product Characteristics prior to use of Lantus. Lantus cartridges and Solostar prefilled pens each contain 300 Units of insulin glargine in 3ml, equivalent to 10.92mg.
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. Do not administer intravenously. Insulin glargine dosage should be individually adjusted. In type 2 diabetes mellitus, Lantus can also be used in combination with orally active antidiabetic medicinal products. Close metabolic monitoring is recommended during, and for a period after, transition from other insulins to Lantus. Dose and timing of other antidiabetic medicines may need to be adjusted. 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. Lantus must not be mixed with other insulins or diluted. Insulin requirements may be diminished in the elderly or patients with renal or hepatic impairment. The safety and efficacy of Lantus has not been established in children below 2 years of age. No data are available.
Contraindications: Hypersensitivity to insulin glargine or any excipients.
Precautions and warnings: 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. 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, potentially resulting in severe hypoglycaemia and loss of consciousness. Risk groups include patients in whom glycaemic control is markedly improved, hypoglycaemia develops gradually, an autonomic neuropathy is present, or in elderly patients. The prolonged effect of subcutaneous insulin glargine may delay recovery from hypoglycaemia. Due to more sustained basal insulin supply with Lantus, less nocturnal but more early morning hypoglycaemia can be expected. Insulin administration may cause insulin antibodies to form. Rarely, this may necessitate dose adjustment. Cases of cardiac failure have been reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure. Patients on this combination should be observed for signs and symptoms of heart failure, weight gain and oedema. Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs.
Pregnancy and lactation: No clinical data on exposed pregnancies from controlled clinical trials are available. A large amount of post-marketing data indicate no specific adverse effects of insulin glargine on pregnancy and no specific malformative nor feto/neonatal toxicity. 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 insulin glargine is excreted in breast milk.
Adverse reactions: Very common: hypoglycaemia. Prolonged or severe hypoglycaemia

may be life-threatening. Common: lipohypertrophy, injection site reactions, including redness, itching, pain, hives, swelling or inflammation. Rarely: immediate-type allergic reactions; which may be associated with generalised skin reactions, angio-oedema, bronchospasm, hypotension and shock and may be life threatening; visual impairment, retinopathy and oedema. Very rare: dysgeusia, myalgia Overdose may lead to severe and sometimes long-term and life-threatening hypoglycaemia. Please consult Summary of Product Characteristics for full details of the recognised side effects with Lantus.
NHS price: 5 x 3ml cartridge £41.50; 5 x 3ml SoloStar £41.50 **Legal category:** POM.
MA holder: Sanofi Aventis Deutschland GmbH, D-65926 Frankfurt am Main, Germany.
MA Numbers: Lantus cartridge: EU/1/00/134/006. Lantus SoloStar : EU/1/00/134/033. Full prescribing information is available from: Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YS. Tel: 01483 505515 or the Sanofi Diabetes Care Line 08000 35 25 25.
Date of PI Revision: April 2015

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/. Adverse events should also be reported to the Sanofi drug safety department on 01483 55 4242.