Lyxumia® (lixisenatide)

Please refer to Summary of Product Characteristics prior to use of Lyxumia. Lyxumia 10 micrograms solution for injection: Each dose (0.2 ml) contains 10 micrograms (mcg) of lixisenatide (50 mcg per ml). Lyxumia 20 micrograms solution for injection: Each dose (0.2 ml) contains 20 micrograms (mg) of lixisenatide (100 mcg per ml).

Indications: Treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control.

Dosage and administration: Lyxumia is to be injected subcutaneously in the thigh, abdomen or upper arm. Starting dose: dosing is initiated at 10 mcg Lyxumia once daily for 14 days. Maintenance dose: a fixed maintenance dose of 20 mcg Lyxumia once daily is started on Day 15. Lyxumia 20 micrograms solution for injection is available for the maintenance dose. Lyxumia is administered once daily, within the hour prior to any meal of the day, preferably the same meal each day. If a dose of Lyxumia is missed, it should be injected within the hour prior to the next meal. The clinical experience in patients with gastroparesis is limited. Limited therapeutic experience in patients with moderate renal impairment (creatinine clearance: 30–50 ml/min) and Lyxumia should be used with caution in this population. There is no therapeutic experience in patients with severe renal impairment (creatinine clearance less than 30 ml/min) or end-stage renal disease and therefore, it is not recommended to use Lyxumia in these populations. The safety and efficacy of Lyxumia in children and adolescents less than 18 years of age have not yet been established. Contraindications: Hypersensitivity to Lyxumia or to any of the excipients Precautions and warnings: No therapeutic experience with Lyxumia in patients with type 1 diabetes mellitus and it should not be used in these patients. Lyxumia should not be used for treatment of diabetic ketoacidosis. Use of glucagon like peptide-1 (GLP-1) receptor agonists has been associated with a risk of developing acute pancreatitis. If pancreatitis is suspected, Lyxumia should be discontinued; if acute pancreatitis is confirmed, Lyxumia should not be restarted. Caution should be exercised in patients with a history of pancreatitis. Lyxumia has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis and therefore, the use of Lyxumia is not recommended in these patients. There is limited therapeutic experience in patients with moderate renal impairment (creatinine clearance: 30–50 ml/min) and no therapeutic experience in patients with severe renal impairment (creatinine clearance less than 30 ml/min) or end-stage renal disease. Lyxumia should be used with caution in patients with moderate renal impairment. Use is not recommended in patients with severe renal impairment or end-stage renal disease. Patients receiving Lyxumia with a sulphonylurea or with a basal insulin may have an increased risk of hypoglycaemia. Lyxumia should not be given in combination with basal insulin and a sulphonylurea due to increased risk of hypoglycaemia. Lyxumia should be used with caution in patients receiving oral medicinal products that require rapid gastrointestinal absorption, require careful clinical monitoring or have a narrow therapeutic ratio. Lyxumia has not been studied in combination with dipetidyl peptidase 4 (DPP-4) inhibitors. There is limited experience in patients with concomitant insulin use. Patients treated with Lyxumia should be advised of the potential risk of dehydration in relation to gastrointestinal adverse reactions and take precautions to avoid fluid depletion. This medicinal product contains metacresol, which may cause allergic reactions. Interactions: Paracetamol: No dose adjustment for paracetamol is required but the delayed max observed when paracetamol is administered 1–4 hours after Lyxumia should be taken into account when a rapid onset of action is required for efficacy. Oral contraceptives: The reduction in C_max is of limited clinical relevance and no dose adjustment for oral contraceptives is required. Atorvastatin: Changes to t1/2 and C_max are not clinically relevant and therefore, no dose adjustment for atorvastatin is required when co-administered with Lyxumia. Warfarin and other coumarin derivatives: Frequent monitoring of INR in patients on warfarin and/or coumarin derivatives is recommended at the time of initiation or ending of Lyxumia treatment. Digoxin: No dose adjustment for digoxin is required when co-administered with Lyxumia. Ramipril: No dose adjustment for ramipril is required when co-administered with Lyxumia. Adverse reactions: Very common: Hypoglycaemia (in combination with a sulphonylurea and/or a basal insulin). Headache. Nausea, vomiting & diarrhoea; These tend to be mostly mild and transient during the first 3 weeks after starting treatment. Thereafter, they progressively diminish over the following weeks. Common: Influenza, upper respiratory tract infection, cystitis & viral infection. Hypoglycaemia (in combination with metformin alone). Dizziness, somnolence, dyspepsia, back pain, injection site pruritus. Uncommon: Anaphylactic reaction and urticaria. Please consult the Summary of Product Characteristics in relation to other adverse reactions. NHS price: Lyxumia 10 mcg: 1 pre-filled pen: £27.07. Lyxumia 20 mcg: 2 pre-filled pens: £54.14. Lyxumia 10 mcg + 20 mcg: 1 pre-filled pen + 1 pre-filled pen: £54.14. Legal category: POM. MA holder: sanofi-aventis group, 54, rue La Boétie, F– 75086 Paris cedex 06, France. Lyxumia 10 mcg: 1 pre-filled pen: EU/1/12/811/001. Lyxumia 20 mcg: 2 pre-filled pens: EU/1/12/811/003. Lyxumia 10 mcg + 20 mcg: 1 pre-filled pen + 1 pre-filled pen: EU/1/12/811/005. Full prescribing information is available from: Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YS. Tel: 0845 372 7101. Date of Revision: June 2014

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 6 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 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 for paediatric populations. 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/1/100/134/006. Lantus SoloStar: EU/1/100/134/033. 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

Apidra® (insulin glulisine)

Please refer to Summary of Product Characteristics prior to use of Apidra. Apidra cartridges and Solostar prefilled pens each contain 300 Units of insulin glulisine in 3ml, equivalent to 10.47mg. Apidra vials contain 1000 Units insulin glulisine in 10ml, equivalent to 34.9mg. Indications: Treatment of diabetes mellitus in adults, adolescents and children of 6 years or above. Dosage and treatment of diabetic ketoacidosis. In case of insufficient gluconeogenesis 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. 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/1/100/134/006. Lantus SoloStar: EU/1/100/134/033. 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

Apidra® (insulin glulisine)

Please refer to Summary of Product Characteristics prior to use of Apidra. Apidra cartridges and Solostar prefilled pens each contain 300 Units of insulin glulisine in 3ml, equivalent to 10.47mg. Apidra vials contain 1000 Units insulin glulisine in 10ml, equivalent to 34.9mg. Indications: Treatment of diabetes mellitus in adults, adolescents and children of 6 years or above. Dosage and
Insulan® (insulin human)

Please refer to Summary of Product Characteristics prior to use of Insulan. Insulan Basal, Comb 15, Comb 25, Comb 50 and Rapid cartridges, in addition to the Insulan Basal and Comb 25 SoloStar pens each contain 300 IU of insulin human in 3ml, equivalent to 10.5mg. Insulan Basal and Comb 25 vials contain 500 IU of insulin human in 5ml, equivalent to 17.5mg. Insulan Rapid contains neutral insulin solution (regular insulin). Insulan Basal contains isophane insulin suspension. Insulan Comb 15, 25 and 50 contain 15% regular and 85% isophane, 25% regular and 75% isophane, and 50% regular and 50% isophane insulin, respectively. Indications: Diabetes mellitus. Insulan Rapid cartridges are also suitable for the treatment of hyperglycaemic coma, ketoacidosis, and for achieving pre-, intra- and post-operative stabilisation. Dosage and administration: Insulin doses and timings should be determined individually. There are no fixed rules for insulin dosage. Average insulin requirement is often 0.5 to 1.0 IU/kg body weight/day. Basal metabolic requirement is 40% to 60% of total daily requirement. Insulan should be injected subcutaneously. Insulan Rapid should be injected 15 to 20 minutes before a meal; Insulan Basal should be injected 45 to 60 minutes before a meal; Insulan Comb 15 and 25 should be injected 30 to 45 minutes before a meal; Insulan Comb 50 should be injected 20 to 30 minutes before a meal. Insulan Rapid cartridges may also be administered intravenously under close medical supervision. Close metabolic monitoring is recommended during, and for a period after, transition from other insulins to Insulan. 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. Insulin requirements may be diminished in the elderly or patients with renal or hepatic impairment. Contra-indications: Hypersensitivity to human insulin or to any excipients. Hypersensitivity to human insulin or to any excipients. Contra-indications: Hypersensitivity to human insulin or to any excipients. Precautions and warnings: Patients hypersensitive to Insulan Rapid, Basal or Comb 15, 25 or 50 for whom no better tolerated preparation is available must only continue treatment under close medical supervision, in conjunction with anti-allergic treatment if necessary. In patients allergic to animal insulin, intradermal skin testing is recommended prior to initiation. Hypoglycaemia may occur. 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 can be developed gradually, an autonomic neuropathy is present, or in elderly patients. Intensified metabolic monitoring is necessary during intercurrent illness. 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 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: There is no clinical data on the use of Insulan in pregnant women. Insulan can be used during breast feeding. Adverse Reactions: Hypoglycaemia is the most frequent adverse reaction. Prolonged or severe hypoglycaemia may be life-threatening. Severe hypoglycaemic attacks, especially if recurrent, may lead to neurological damage. Common: oedema, injection site urticaria. Immediate type allergic reactions to insulin or to the excipients may be life-threatening (hypotension, angioneurotic oedema, bronchospasm, generalised skin reactions). Insulin administration may cause insulin antibodies to form and, in rare cases, necessitate adjustment of the insulin dose.

Insulan Rapid
- 5 cartridges of 3ml £17.50 EU/197/030/030
- 1 vial of 5ml £5.61 EU/197/030/033

Insulan Basal
- 5 cartridges of 3ml £17.50 EU/197/030/035
- 5 SoloSTAR pens of 3ml £19.80 EU/197/030/048

Insulan Comb 15
- 5 cartridges of 3ml £17.50 EU/197/030/040

Insulan Comb 25
- 1 vial of 5ml £5.61 EU/197/030/043
- 5 cartridges of 3ml £17.50 EU/197/030/045
- 5 SoloSTAR pens of 3ml £19.80 EU/197/030/050

Insulan Comb 50
- 5 cartridges of 3ml £17.50 EU/197/030/050

Legal category: POM. MA holder: Sanofi Aventis Deutschland GmbH, D-65926 Frankfurt am Main, Germany. Full prescribing information is available from: Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YS. Tel: 0845 372 7101. Date of Revision: October 2014

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.mhra.gov.uk. Adverse events should also be reported to the Sanofi drug safety department on 01483 554242.