Prescribing Information

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 (mcg) 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. 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. There have been few reported events of acute pancreatitis with Lyxumia although a causal relationship has not been established. 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 no therapeutic experience in patients with severe renal impairment (creatinine clearance less than 30 ml/min) or end-stage renal disease. 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 dipeptidyl peptidase 4 (DPP-4) inhibitors.

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.

Pregnancy and Lactation: Not recommended in women of childbearing potential not using contraception. Should not be used in pregnancy/ breast-feeding.

Interactions: Paracetamol: No dose adjustment for paracetamol is required but the delayed t_{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 t_{max} 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 (nausea and vomiting mostly mild and transient occuring during the first 3 weeks after starting treatment.) **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, urticaria. Please consult the Summary of Product Characteristics in relation to other adverse reactions

NHS price: Lyxumia 10 mcg: 1 pre-filled pen: £31.67, Lyxumia 20 mcg: 2 pre-filled pens: £57.93, Lyxumia 10 mcg + 20 mcg: 1 pre-filled pen + 1 pre-filled pen: £57.93
Legal category: POM.
MA holder: sanofi-aventis groupe, 54, rue La Boétie, F – 75008 Paris, France
MA Number(s): 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: May 2016

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