Prescribing Information: Lyxumia® (lixisenatide) solution for injection

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

Presentations: Lyxumia 20mcg solution for injection contains 20mcg of lixisenatide (100mcg per ml) per dose.
Indications: Lyxumia is indicated for the 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 must be injected subcutaneously in the thigh, abdomen or upper arm, once daily, within the hour prior to any meal of the day. It is preferable that the prandial injection of Lyxumia is performed before the same meal every day, when the most convenient meal has been chosen. If a dose is missed, it should be injected within the hour prior to the next meal. Lyxumia should not be administered intravenously or intramuscularly. Lyxumia should only be used for continuation of treatment for existing patients who are already maintained on a fixed dose of 20mcg Lyxumia once daily. Lyxumia 20mcg must not be used to initiate treatment in new patients.
Special Populations: Elderly and hepatic impairment: No dose adjustment required. Renal impairment: *Mild/Moderate:* No dose adjustment required. *Severe or end-stage renal disease:* Not recommended. Paediatric population (<18 years): Safety and efficacy has not been established.
Contraindications: Hypersensitivity to Lyxumia or to any of the excipients.
Precautions and Warnings: There is 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. Acute pancreatitis: Use of glucagon-like peptide-1 (GLP-1) receptor agonists has been associated with a risk of developing acute pancreatitis. Patients should be informed of the characteristic symptoms of acute pancreatitis: persistent, severe abdominal pain. If pancreatitis is suspected, Lyxumia should be discontinued; if acute pancreatitis is confirmed it should not be restarted. Caution should be exercised in patients with a history of pancreatitis. Severe gastrointestinal (GI) disease: Use of GLP-1 receptor agonists may be associated with GI adverse reactions. Lyxumia has not been studied in patients with severe GI disease, including severe gastroparesis. Use of Lyxumia is not recommended in these patients. Hypoglycaemia: Lyxumia should not be given in combination with basal insulin and a sulphonylurea due to increased risk of hypoglycaemia. Reduction of the dose of the sulphonylurea or the basal insulin may be considered to reduce the risk of hypoglycaemia. Dehydration: 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. Excipients: This medicine contains metacresol, which may cause allergic reactions. This medicine is essentially "sodium-free". ***Interactions:*** The delay of gastric emptying with Lyxumia may reduce the rate of absorption of orally administered medicinal products. Patients receiving medicinal products of either a narrow therapeutic ratio or medicinal products that require careful clinical monitoring should be followed closely, especially at the time of initiation of Lyxumia treatment. For oral medicinal products that are particularly dependent on threshold concentrations for efficacy, or gastro-resistant formulations containing substances sensitive to stomach degradation such as antibiotics, patients should be advised to take those medicinal products at least 1 hour before or 4 hours after lixisenatide injection. Lyxumia has not been studied in combination with dipeptidyl peptidase 4 (DPP-4) inhibitors. Paracetamol: No dose adjustment for paracetamol is required, however a delayed T_{max} was observed when paracetamol was administered 1 – 4 hours after Lyxumia. Warfarin and other coumarin derivatives: No dose adjustment for warfarin is required when co-administered with Lyxumia; however, frequent monitoring of INR in patients on warfarin and/or coumarin derivatives is recommended at the time of initiation or ending of Lyxumia treatment. ***Fertility, pregnancy and lactation:*** Animal studies do not indicate direct harmful effects with respect to fertility. Lyxumia is not recommended in women of childbearing potential not using contraception. Studies in animals have shown reproductive toxicity. Lyxumia should not be used during pregnancy. If a patient wishes to become pregnant, or pregnancy occurs, treatment with Lyxumia should be discontinued. Lyxumia should not be used during breast-feeding.
Adverse reactions: Very common: Hypoglycaemia (in combination with a sulphonylurea and / or a basal insulin), headache, nausea, vomiting, diarrhoea. 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. Rare: Delayed gastric emptying. *Prescribers should consult the SmPC in relation to other adverse reactions.*
Legal category: POM.
GB List price and Marketing Authorisation Number:
2 x pre-filled pens (PLGB 04425/0832): £57.93
Marketing Authorisation Holder: Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK
Further information is available from: Medical Information, Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. uk-medicalinformation@sanofi.com
Date of preparation: November 2022.
MAT-XU-2204701 (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 drug safety department Tel: 0800 0902314. Alternatively, send via email to UK-drugsafety@sanofi.com