Lixisenatide (Lyxumia®)

Prescribing Information Sheet

This document provides general prescribing information on the use of lixisenatide. For the most up to date information, consult the summary of product characteristics (SPC)– http://www.medicines.org.uk/emc/

For information on place in therapy, prescribing and monitoring requirements and responsibilities, please see separate 'Overarching Shared Care Guideline for the use of Glucagon-like peptide 1 (GLP 1) agonists.'

Licensed Indication	Lixisenatide 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. (See SPC for further details on which combinations have data to support use – Decision to prescribe is left to the discretion of the clinician).
Drug dose	**ADULT** over 18 years, initially 10 micrograms once daily within 1 hour before the first meal of the day or the evening meal for 14 days, increased to 20 micrograms once daily thereafter. It is preferable that the prandial injection of lixisenatide is performed before the same meal every day, when the most convenient meal has been chosen. If a dose of lixisenatide is missed, it should be injected within the hour prior to the next meal. **Counselling** If a dose is missed, inject within 1 hour before the next meal—do not administer **after** a meal. Some oral medications should be taken at least 1 hour before or 4 hours after lixisenatide injection—consult product literature for details. **Added to other hypoglycaemic agents** When lixisenatide is added to existing metformin therapy, the current metformin dose can be continued unchanged. When lixisenatide is added to existing therapy of a sulphonylurea or a basal insulin, a reduction in the dose of the sulphonylurea or the basal insulin may be considered to reduce the risk of hypoglycaemia. Lixisenatide should not be given in combination with basal insulin and a sulphonylurea due to increased risk of hypoglycaemia.
Drug modifications in Special Populations	**Elderly** • No dose adjustment is needed based on age. **Renal impairment** • Use with caution if eGFR 30–50 mL/minute/1.73 m^2; avoid if eGFR less than 30 mL/minute/1.73 m^2—no information available. • Do not use in patients with end stage renal disease. • No dose adjustment is required for patients with mild or moderate renal impairment.

	Hepatic impairment • No dose adjustment is needed in patients with hepatic impairment.
Administration details	• Lixisenatide should be injected subcutaneously into the thigh, abdomen or upper arm. • Lixisenatide should not be administered intravenously or intramuscularly. • Injection site should be rotated.
Formulations	Injection, 50 micrograms/mL, 10 micrograms/dose prefilled pen (14 doses); 100 micrograms/mL, 20 micrograms/dose prefilled pen (14 doses) × 2; treatment initiation pack, 10 micrograms/dose prefilled pen and 20 micrograms/dose prefilled pen.
Contra-indications / Cautions	**Contraindications –** Ketoacidosis, severe gastro-intestinal disease. **Cautions -** discontinue if symptoms of acute pancreatitis (persistent, severe abdominal pain). Clinicians should refer to the current electronic BNF or Summary of Product Characteristics (SPC's) for full details www.bnf.org/products/bnf-online www.medicines.org.uk/emc
Side effects	Lyxumia® is denoted a black triangle (▼) drug. Report all side effects using the yellow card scheme. http://yellowcard.mhra.gov.uk/ Clinicians should refer to the Summary of Product Characteristics (SPC) and current electronic BNF for full details www.bnf.org/products/bnf-online www.medicines.org.uk/emc **Very Common Side Effects** • Hypoglycaemia (in combination with a sulphonylurea and / or a basal insulin) • Headache • Nausea and Vomiting • Diarrhoea Further Information: Discontinue if symptoms of acute pancreatitis (persistent, severe abdominal pain).
Drug Interactions	Lixisenatide has the following interaction information (eBNF) **Note:** Other drugs administered orally may need to be taken at least 1 hour before or 4 hours after lixisenatide injection, or taken with a meal when lixisenatide is not administered, to minimise possible interference with absorption Paracetamol — lixisenatide possibly reduces the absorption of paracetamol when given 1 to 4 hours before paracetamol See also information above re use in combination with sulphonylurea or insulin. **N.B.** Lixisenatide should not be given in combination with basal insulin and a sulphonylurea due to increased risk of hypoglycaemia Lixisenatide belongs to **Antidiabetics** and will have the interactions listed in the BNF relating to this class of drugs. Clinicians should check the Summary of Product Characteristics (SPC) and the current electronic BNF for a full list of potential drug

	interactions before starting any new medication or when stopping any existing medication. www.medicines.org.uk/emc www.bnf.org/products/bnf-online
Pregnancy and Breastfeeding	Pregnancy There are no adequate data from the use of lixisenatide in pregnant women. Studies in animals have shown reproductive toxicity. The potential risk for humans is unknown. Lixisenatide should not be used during pregnancy. The use of insulin is recommended instead. If a patient wishes to become pregnant, or pregnancy occurs, treatment with lixisenatide should be discontinued. Breast-feeding It is unknown if lixisenatide is excreted in human milk. Lixisenatide should not be used during breast-feeding.
Storage Conditions	Lixisenatide should be stored in a refrigerator (2°C - 8°C). After its first use, lixisenatide should be stored below 30°C. Lixisenatide should not be frozen under any circumstances. In addition, the pen on the cap should be kept on when the device is not in use, in order to protect the active ingredient from light.

References:-

1. Summary of Product Characteristics for Lixumia® (Lxisenatide), accessed 24/11/16, http://www.medicines.org.uk/emc/
2. EBNF, accessed 24/11/16, https://www.evidence.nhs.uk/formulary/bnf/current/6-endocrine-system/61-drugs-used-in-diabetes/612-antidiabetic-drugs/6123-other-antidiabetic-drugs/lixisenatide