For the use only of a Registered Medical Practitioner , Hospital, Laboratory

Lixisenatide Pre-filled Solution for Injection
LYXUMIA™

Abridged Prescribing Information

COMPOSITION
- Each dose (0.2 mL) contains 10mcg lixisenatide [3mL cartridge in a green prefilled pen]
- Each dose (0.2 mL) contains 20mcg lixisenatide [3mL cartridge in a burgundy (purple) prefilled pen]

THERAPEUTIC INDICATIONS
LYXUMIA™ is indicated for treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in patients who are not controlled on existing therapy: In combination with the following oral antidiabetics: metformin, a sulphonylurea, or a combination of these agents. In combination with a basal insulin: alone, in combination with metformin, or in combination with a sulphonylurea.

DOSAGE AND ADMINISTRATION
The starting dose is 10 mcg once daily for 14 days. Dose should be increased to 20 mcg once daily which is the maintenance dose. When added to existing metformin therapy, the current metformin dose can be continued unchanged. When added to existing therapy of a sulphonylurea or a combination of a sulphonylurea and a basal insulin, a reduction in the dose of the sulphonylurea or the basal insulin may be considered to reduce the risk of hypoglycaemia.

Special Populations: The safety and effectiveness of LYXUMIA™ in pediatric patients below the age of 18 years have not yet been established. No dose adjustment is required based on age, in case of hepatic impairment, or in mild (creatinine clearance: 60-90 ml/min) and moderate (creatinine clearance: 30-60 ml/min) renal impairment. There is no therapeutic experience in patients with severe renal impairment (creatinine clearance < 30 ml/min) or end-stage renal disease and hence not recommended to use in these populations.

Administration: LYXUMIA™ is administered once daily within the hour prior to any meal of the day, preferable that it is injected before the same meal every day, when the most convenient meal has been chosen. Should not be administered intravenously or intramuscularly.

SAFETY-RELATED INFORMATION
CONTRAINDICATIONS: In patients with known hypersensitivity to lixisenatide or to any of the inactive ingredients in the formulation

WARNINGS : Use In Type 1 Diabetes : No therapeutic experience in patients with type 1 diabetes mellitus and it should not be used in these patients and for treatment of diabetic ketoacidosis. **Risk of 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. If pancreatitis is suspected, LYXUMIA™should be discontinued; if acute pancreatitis is confirmed, LYXUMIA™should not be restarted. Use with caution in patients with a history of pancreatitis**.**

PRECAUTIONS: ***Use in patients with severe gastroparesis-*** Has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis and therefore not recommended. ***Risk of hypoglycaemia-***Patients receiving LYXUMIA™ with a sulphonylurea or with a combination of a basal insulin and a sulphonylurea may have an increased risk of hypoglycaemia.

PREGNANCY & LACTATION: Should not be used during pregnancy and breastfeeding.

ADVERSE REACTIONS: The most frequently reported adverse reactions during Phase III studies are: Very Common - Nausea, vomiting, diarrhoea, headache, Symptomatic hypoglycaemia,. Common : Influenza, upper respiratory tract infections, dizziness, dyspepsia, back pain.

For full prescribing information please write to : Sanofi – Synthelabo (India) Private Ltd., Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

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Reference: Lixisenatide CCDS V 5.0 dated September 2015