SEMALIX™

For the use of only a Endocrinologist or Internal Medicine Specialist only

Abbreviated Prescribing information for SEMALIX™ [Semaglutide Injection 2mg/3mL (0.68mg/mL), 4mg/3mL (1.34mg/mL) & 8mg/3mL (2.68 mg/mL) Prefilled Pen]
[Please refer the complete prescribing information available at www.torrentpharma.com]

WARNING: RISK OF THYROID C-CELL TUMORS

- In rodents, semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether semaglutide causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined.
- Semaglutide is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of semaglutide and inform them of symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Semaglutide.

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Semaglutide is a GLP-1 analogue with 94% sequence homology to human GLP-1. Semaglutide acts as a GLP-1 receptor agonist that selectively binds to and activates the GLP-1 receptor, the target for native GLP-1. GLP-1 is a physiological hormone that has multiple actions on glucose, mediated by the GLP- 1 receptors. The principal mechanism of protraction resulting in the long half-life of semaglutide is albumin binding, which results in decreased renal clearance and protection from metabolic degradation. Furthermore, semaglutide is stabilized against degradation by the DPP-4 enzyme. Semaglutide reduces blood glucose through a mechanism where it stimulates insulin secretion and lowers glucagon secretion, both in a glucose-dependent manner. Thus, when blood glucose is high, insulin secretion is stimulated, and glucagon secretion is inhibited. The mechanism of blood glucose lowering also involves a minor delay in gastric emptying in the early postprandial phase.

INDICATIONS: Semaglutide is indicated for the treatment of adults with insufficiently controlled type 2 diabetes as an adjunct to diet and exercise: • as monotherapy, when metformin-based therapy is considered inappropriate due to intolerance or contraindications. • in addition to the other medicinal products for the treatment of diabetes.

DOSAGE AND ADMINISTRATION: The starting dose is 0.25 mg semaglutide once weekly. After 4 weeks the dose should be increased to 0.5 mg once weekly. After at least 4 weeks with a dose of 0.5 mg once weekly, the dose can be increased to 1 mg once weekly to further improve glycaemic control. After at least 4 weeks with a dose of 1 mg once weekly, the dose can be increased to 2 mg once weekly to further improve glycaemic control. Semaglutide 0.25 mg is not a maintenance dose. Weekly doses higher than 2 mg are not recommended. When Semaglutide is added to existing metformin can be continued unchanged. Subcutaneous use. Semaglutide is to be injected subcutaneously in the abdomen, in the thigh or in the upper arm. The injection site can be changed without dose adjustment. Semaglutide should not be administered intravenously or intramuscularly. Semaglutide is to be administered once weekly at any time of the day, with or without meals.

CONTRAINDICATION: Semaglutide is contraindicated in patients with: • A personal or family history of MTC or in patients with MEN 2. • A serious hypersensitivity reaction to semaglutide or to any of the excipients in Semaglutide.

WARNINGS & PRECAUTIONS: Semaglutide should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Semaglutide is not a substitute for insulin. Diabetic ketoacidosis has been reported in insulin-dependent patients whom had rapid discontinuation or dose reduction of insulin when treatment with a GLP-1 receptor agonist is started. There is no experience in patients with congestive heart failure NYHA class IV and Semaglutide is therefore not recommended in these patients. Cases of pulmonary aspiration have been reported in patients receiving GLP-1 receptor agonists undergoing general anaesthesia or deep sedation. Therefore, the increased risk of residual gastric content due to delayed gastric emptying should be considered prior to performing procedures with general anaesthesia or deep sedation. Use of GLP-1 receptor agonists may be associated with gastrointestinal adverse reactions. This should be considered when treating patients, with impaired renal function as nausea, vomiting, and diarrhoea may cause dehydration which could cause a deterioration of renal function. Semaglutide has not been studied in patients with a history of pancreatitis, and should be used with caution in these patients. If pancreatitis is suspected, Semaglutide should be discontinued. If the diagnosis of pancreatitis is confirmed, Semaglutide should not be restarted. Patients treated with Semaglutide in combination with a sulfonylurea or insulin may have an increased risk of hypoglycaemia. Patients reporting a sudden loss of vision (including partial loss) should be urgently referred for ophthalmological examination and treatment with Semaglutide should be discontinued if NAION is confirmed. Caution should be exercised when using Semaglutide in patients with diabetic retinopathy treated with insulin. These patients should be monitored closely and treated according to clinical guidelines.

DRUG INTERACTIONS: Semaglutide delays gastric emptying and has the potential to impact the rate of absorption of concomitantly administered oral medicinal products. Semaglutide should be used with caution in patients receiving oral medicinal products that require rapid gastrointestinal absorption. Semaglutide delays the rate of gastric emptying as assessed by paracetamol pharmacokinetics during a standardised meal test. Upon initiation of semaglutide treatment in patients on warfarin or other coumarin derivatives, frequent monitoring of INR is recommended.

ADVERSE REACTIONS: Abdominal distension, Abdominal pain upper, Constipation, Diarrhoea, Dyspepsia, Eructation, Gastritis, Hyperchlorhydria, Nausea, Vomiting, Asthenia, Decreased appetite, Fatigue, Injection site swelling, Pain, Pyrexia, Nasopharyngitis, Rhinitis, Hypoglycaemia, Dizziness, Headache, Cough, rhinorrhea, Upper Respiratory Tract Infection (URI).

MARKETED BY:

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

IN/SEMALIX™ Injection 2mg/3mL, 4mg/3mL and 8mg/3mL/APR-2026/01/ABPI

(Additional information is available on request)