SEMBOLIC TAB™

To be sold by retail on the prescription of endocrinologist or internal medicine specialists only

Abbreviated Prescribing information for SEMBOLIC TAB™ [Semaglutide Tablets 3 mg, 7 mg & 14 mg]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Semaglutide acts as a GLP-1 receptor agonist that selectively binds to and activates the GLP-1 receptor, the target for native GLP-1. Semaglutide reduces blood glucose in a glucose-dependent manner by stimulating insulin secretion and lowering glucagon secretion when blood glucose is high. The mechanism of blood glucose lowering also involves a minor delay in gastric emptying in the early postprandial phase. During hypoglycaemia, semaglutide diminishes insulin secretion and does not impair glucagon secretion.

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

DOSAGE AND ADMINISTRATION: The starting dose of semaglutide is 3 mg once daily for one month. The maximum recommended single daily dose of semaglutide is 14 mg. Semaglutide should always be used as one tablet per day. The recommended single daily maintenance doses are 7 mg or 14 mg. If a dose is missed, the missed dose should be skipped and the next dose should be taken the following day. Semaglutide is a tablet for once-daily oral use. This medicinal product should be taken on an empty stomach after a recommended fasting period of at least 8 hours. It should be swallowed whole with a sip of water (up to half a glass of water equivalent to 120 ml). Tablets should not be split, crushed, or chewed, as it is not known whether this impacts absorption of semaglutide. Patients should wait at least 30 minutes before eating, drinking, or taking other oral medicinal products. Waiting less than 30 minutes decreases the absorption of semaglutide**.**

CONTRAINDICATION: Semaglutide is contraindicated in patients with: •A personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). • 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 contraindicated in patients with a personal or family history of MTC or in patients with 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). Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with GLP-1 receptor agonists, including semaglutide. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy. Patients receiving semaglutide in combination with an insulin secretagogue (e.g., sulfonylurea) or insulin may have an increased risk of hypoglycemia, including severe hypoglycemia. Monitor renal function in patients reporting adverse reactions to semaglutide that could lead to volume depletion, especially during dosage initiation and escalation of semaglutide. Use of semaglutide has been associated with gastrointestinal adverse reactions, sometimes severe. semaglutide is contraindicated in patients with a prior serious hypersensitivity reaction to semaglutide or to any of the excipients in semaglutide. Use caution in a patient with a history of angioedema or anaphylaxis with another GLP-1 receptor agonist because it is unknown whether such patients will be predisposed to anaphylaxis with semaglutide**.**

DRUG INTERACTIONS: Semaglutide delays gastric emptying which may influence the absorption of other oral medicinal products. Monitoring of thyroid parameters should be considered when treating patients with semaglutide at the same time as levothyroxine. Cases of decreased INR have been reported during concomitant use of acenocoumarol and semaglutide. Upon initiation of semaglutide treatment in patients on warfarin or other coumarin derivatives, frequent monitoring of INR is recommended.

ADVERSE REACTIONS: Hypersensitivity, anaphylactic reaction, hypoglycaemia when used with insulin or sulfonylurea, hypoglycaemia when used with other oral antidiabetic products, decreased appetite, dizziness, headache, dysgeusia, dysesthesia, diabetic retinopathy complications, increased heart rate, nausea, diarrhoea, vomiting, abdominal pain, abdominal distension, constipation, dyspepsia, gastritis, gastro-oesophageal reflux

disease, flatulence, eructation, delayed gastric emptying, acute pancreatitis, intestinal obstruction, cholelithiasis, acute kidney injury, alopecia, fatigue, increased lipase, increased amylase, weight decreased, acute pancreatitis, and hyperchlorhydria.

MARKETED BY:

Torrent Pharmaceuticals Limited.

IN/SEMBOLIC TAB™ (3 mg, 7 mg, 14 mg)/Feb-2026/01/ABPI

(Additional information is available on request)