SEMBOLIC™

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

Abbreviated Prescribing information for SEMBOLIC™ [Semaglutide Injection 15mg/3mL]
[Please refer the complete prescribing information available at www.torrentpharma.com]

WARNING: RISK OF THYROID C-CELL TUMORS

- In rodents, semaglutide causes 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 the 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 of MTC and symptoms of thyroid tumors.

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: SEMBOLIC 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 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 glucan secretion is inhibited. The mechanism of blood glucose lowering also involves a minor delay in gastric emptying in the early postprandial phase.

INDICATIONS: ***T2DM:*** SEMBOLIC 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. *Limitations of Use*: •Has not been studied in patients with a history of pancreatitis. Consider another antidiabetic therapy. •Not for treatment of type 1 diabetes mellitus. ***CHRONIC WEIGHT MANAGEMENT:*** SEMBOLIC is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: •30 kg/m2 or greater (obesity) or, •27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia). *Limitations of Use*: •SEMBOLIC should not be used in combination with other semaglutide-containing products or any other GLP-1 receptor agonist. •The safety and efficacy of coadministration with other products for weight loss have not been established. •SEMBOLIC has not been studied in patients with a history of pancreatitis.

DOSAGE AND ADMINISTRATION: ***T2DM:*** •Inspect SEMBOLIC visually before use. It should appear clear and colorless. Do not use SEMBOLIC is particulate matter and coloration is seen. •Administer SEMBOLIC once weekly, on the same day each week, at any time of the day, with or without meals. •Inject SEMBOLIC subcutaneously to the abdomen, thigh, or upper arm. Instruct patients to use a different injection site each week when injection in the same body region. •When using SEMBOLIC with insulin, instruct patients to administer as separate injections and to never mix the products. It is acceptable to inject SEMBOLIC and insulin in the same body region, but the injections should not be adjacent to each other. *Recommended Dosage*: Initiate SEMBOLIC with a dosage of 0.25 mg injected subcutaneously once weekly for 4 weeks. After 4 weeks on the 0.25 mg dosage, increase the dosage to 0.5 mg once weekly. The maximum recommended dosage is 2 mg once weekly. ***CHRONIC WEIGHT MANAGEMENT***: •In patients with type 2 diabetes, monitor blood glucose prior to starting SEMBOLIC and during SEMBOLIC treatment. •Prior to initiation of SEMBOLIC, train patients on proper injection technique. • Inspect SEMBOLIC visually prior to each injection. Only use if solution is clear, colorless and contains no particles. •Administer SEMBOLIC once weekly, on the same day each week, at any time of the day, with or without meals. •Inject SEMBOLIC subcutaneously in the abdomen, thigh, or upper arm. The time of day and the injection site can be changed without dose adjustment. *Recommended Dosage*: Initiate SEMBOLIC with a dosage of 0.25 mg injected subcutaneously once-weekly. If patients do not tolerate a dose during dosage escalation, consider delaying dosage escalation for 4 weeks.

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).

• A serious hypersensitivity reaction to semaglutide or to any of the excipients in SEMBOLIC. Serious hypersensitivity reactions including anaphylaxis and angioedema have been reported with SEMBOLIC.

WARNINGS & PRECAUTIONS: SEMBOLIC 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 SEMBOLIC and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). After initiation of SEMBOLIC, observe patients carefully for signs and symptoms of pancreatitis. If pancreatis is suspected, SEMBOLIC should be discontinued and appropriate management initiated; if confirmed, SEMBOLIC should not be restarted. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy. SEMBOLI**C** pens must never be shared between patients, even if the needle is changed. Pen-sharing poses a risk for transmission of blood-borne pathogens. Patients receiving SEMBOLIC in combination with an insulin secretagogue (e.g., sulfonylurea) or insulin may have an increased risk of hypoglycemia, including severe hypoglycemia. Monitor renal function when initiating or escalating doses of SEMBOLIC in patients reporting severe adverse gastrointestinal reactions. 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 SEMBOLIC. Substantial or rapid weight loss can increase the risk of cholelithiasis; however, the incidence of acute gallbladder disease was greater in SEMBOLIC-treated patients than in placebo-treated patients, even after accounting for the degree of weight loss. If patients experience a sustained increase in resting heart rate, discontinue SEMBOLIC. Discontinue SEMBOLIC in patients who experience suicidal thoughts or behaviors. Avoid SEMBOLIC in patients with a history of suicidal attempts or active suicidal ideation.

DRUG INTERACTIONS: *Concomitant Use with an Insulin Secretagogue (e.g., Sulfonylurea) or with Insulin*: When initiating Semaglutide, consider reducing the dose of concomitantly administered insulin secretagogue (such as sulfonylureas) or insulin to reduce the risk of hypoglycemia. *Oral Medications*: Semaglutide causes a delay of gastric emptying, and thereby has the potential to impact the absorption of concomitantly administered oral medications.

ADVERSE REACTIONS: ***T2DM:*** nausea, vomiting, diarrhea, abdominal pain and constipation, reduction in blood sugar, dizziness, eye complications, difficulty in digestion, heartburn, gall-bladder stone, generalized weakness, increase pancreatic enzymes, injection site reaction, increased heart rate, acute pancreatitis, allergic reaction, intestinal obstruction, Fatigue, Dysgeusia and Dizziness. ***CHRONIC WEIGHT MANAGEMENT:*** Headache, Dyspepsia, Abdominal Distension, Eructation, Flatulence, Gastroenteritis, Gastroesophageal Reflux disease, Gastritis, Gastroenteritis Viral, Hair Loss, Dysesthesiae, Appendicitis.

MARKETED BY:

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

IN/SEMBOLIC™ Injection 15mg/3mL/MAR-2026/01/ABPI

(Additional information is available on request)