Semazic™

Semaglutide

COMPOSITION

Semazic™ 0.25 mg Injection: Each pre-filled syringe contains Semaglutide INN 0.25 mg in 0.188 ml solution for injection.
Semazic™ 0.50 mg Injection: Each pre-filled syringe contains Semaglutide INN 0.50 mg in 0.375 ml solution for injection.

PHARMACOLOGY

Semaglutide is a GLP-1 analogue with 94% sequence as same as to human GLP-1. Semaglutide acts as a GLP-1 receptor agonist that selectively binds to and activates the GLP-1 receptor. 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. During hypoglycemia, Semaglutide diminishes insulin secretion and does not impair glucagon secretion. Semaglutide reduces body weight and body fat mass by an overall reduced appetite.

INDICATIONS

- An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
- To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease

DOSAGE & 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 glycemic control. Semaglutide is to be administered once weekly at any time of the day with or without meals. Semaglutide is to be injected subcutaneously in the abdomen, thigh or in upper arm. The injection site can be changed without dose adjustment. Semaglutide should not be administered intravenously or intramuscularly. The day of weekly administration can be changed if necessary as long as the time between two doses is at least 3 days (>72 hours). After selecting a new dosing day, once weekly dosing should be continued.

DOSE ADJUSTMENT

When Semaglutide is added to existing metformin and/or thiazolidinedione therapy, the current dose of metformin and/or thiazolidinedione can be continued unchanged. When Semaglutide is added to existing therapy of sulfonylurea or insulin, a reduction in the dose of sulfonylurea or insulin should be considered to reduce the risk of hypoglycemia. Self monitoring in blood glucose is not needed in order to adjust the dose of Semaglutide. Blood glucose self-monitoring is necessary to adjust the dose of sulfonylurea and insulin particularly when Semaglutide is started and insulin is reduced.
Missed dose: If a dose is missed, it should be administered as soon as possible and within 5 days after the missed dose. If more than 5 days have passed, the missed dose should be skipped and the next dose should be administered on the regular scheduled day. In each case, patients can then resume their regular once weekly dosing schedule.

CONTRAINDICATIONS

- Personal or family history of MTC (medullary thyroid carcinoma) or in patients with MEN 2 (Multiple Endocrine Neoplasia syndrome type 2)
- Hypersensitivity to the active substance or to any of the excipients.

WARNINGS & PRECAUTIONS

Diabetic ketoacidosis: Semaglutide should not be used in type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.
Pancreatitis: Semaglutide should be discontinued promptly if pancreatitis is suspected and it should not be restarted if pancreatitis is confirmed.
Diabetic Retinopathy: Patient with diabetic retinopathy should be monitored.

SIDE EFFECTS

Sometimes hypoglycemia can occur when used with insulin or sulfonylurea. The most frequent adverse reactions are gastrointestinal disorder, nausea, diarrhoea, vomiting, abdominal pain and constipation. In general these reactions are mild or moderate in severity and of short duration. Beside these allergic reaction, injection site reaction, lipodystropy, pruritus and rash may occur.

DRUG INTERACTION

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.

USE IN SPECIFIC POPULATION

Elderly: No dose adjustment is required based on age.
Renal impairment: No dose adjustment is required for patients with mild moderate or severe renal impairment. Semaglutide is not recommended for use in patients with end-stage renal disease.
Hepatic impairment: No dose adjustment is required for patients with hepatic impairment.
Pregnancy and Lactation: Semaglutide should not be used during pregnancy. If a patient wishes to become pregnant Semaglutide should be discontinued at least 2 months before a planned pregnancy. As a risk to a breast-fed child cannot be excluded, Semaglutide should not be used during breast-feeding.
Paediatric population: The safety and efficacy of Semaglutide in children and adolescents below 18 years have not yet been established.

STORAGE CONDITION

Store at 2ºC to 8ºC (in a refrigerator). Do not freeze. Keep out of reach of children.

HOW SUPPLIED

Semazic™ 0.25 mg Injection: Each box contains 1 pre-filled syringe of Semaglutide 0.25 mg Injection in blister pack.
Semazic™ 0.50 mg Injection: Each box contains 1 pre-filled syringe of Semaglutide 0.50 mg Injection in blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS PLC.
BANGLADESH