Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Name of the medicinal product: SEMAGLO 0.50 Injection (0.50 mg/dose)
Generic name: Semaglutide Solution for Injection

2. Qualitative and quantitative composition

Each pre-filled syringe contains 0.50 mg of semaglutide in 0.375 mL of solution (1.34 mg/mL).
For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Solution for injection.
Clear, colourless solution.

4. Clinical particulars

4.1 Therapeutic indications

Semaglutide injection is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus.

Limitations of use

Semaglutide injection is not recommended as first-line therapy for patients who have inadequate glycaemic control on diet and exercise, because of the uncertain relevance of rodent C-cell tumour findings to humans.
Semaglutide injection has not been studied in patients with a history of pancreatitis. Other antidiabetic therapies should be considered in patients with a history of pancreatitis.
Semaglutide injection is not a substitute for insulin. It is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of patients with diabetic ketoacidosis, as it would not be effective in these settings.

4.2 Posology and method of administration

Posology

Treatment should be started with a 0.25 mg subcutaneous injection once weekly for 4 weeks. The 0.25 mg dose is intended for treatment initiation and is not effective for glycaemic control.
After 4 weeks on the 0.25 mg dose, the dosage should be increased to 0.5 mg once weekly.
If additional glycaemic control is needed after at least 4 weeks on the 0.5 mg dose, the dosage may be increased to 1 mg once weekly. The maximum recommended dosage is 1 mg once weekly.
Semaglutide injection should be administered once weekly, on the same day each week, at any time of day, with or without meals. The day of weekly administration can be changed if necessary, provided that the time between two doses is at least 2 days (more than 48 hours).

4.3 Contraindications

Semaglutide injection is contraindicated in patients with:

A personal or family history of medullary thyroid carcinoma, or patients with Multiple Endocrine Neoplasia syndrome type 2.

Known hypersensitivity to semaglutide or to any of the eproduct component

4.4 Special warnings and precautions for use

Risk of thyroid C-cell tumours

In mice and rats, semaglutide caused a dose-dependent and treatment-duration-dependent increase in the incidence of thyroid C-cell tumours (adenomas and carcinomas) after lifetime exposure at clinically relevant plasma exposures.

Pancreatitis

In glycaemic control trials, acute pancreatitis was confirmed by adjudication in 7 semaglutide-treated patients (0.3 cases per 100 patient years) versus 3 comparator-treated patients (0.2 cases per 100 patient years). One case of chronic pancreatitis was confirmed in a semaglutide-treated patient. In a 2-year trial, acute pancreatitis was confirmed by adjudication in 8 semaglutide-treated patients (0.27 cases per 100 patient years) and 10 placebo-treated patients (0.33 cases per 100 patient years), both on a background of standard of care.

Diabetic retinopathy complications

In a 2-year trial involving patients with type 2 diabetes and high cardiovascular risk, more events of diabetic retinopathy complications occurred in patients treated with semaglutide (3.0%) compared with placebo (1.8%). The absolute risk increase was larger among patients with a history of diabetic retinopathy at baseline (semaglutide 8.2%, placebo 5.2%) than among patients without a known history of diabetic retinopathy (semaglutide 0.7%, placebo 0.4%).

4.5 Interaction with other medicinal products and other forms of interaction

The risk of hypoglycaemia is increased when semaglutide injection is used in combination with insulin secretagogues (e.g. sulfonylureas) or insulin. The risk may be lowered by a reduction in the dose of the sulfonylurea, other concomitantly administered insulin secretagogue, or insulin.

Oral medicinal products

Semaglutide injection causes a delay of gastric emptying and thereby has the potential to affect the absorption of concomitantly administered oral medicinal products. In clinical pharmacology trials, semaglutide did not affect the absorption of orally administered medicinal products to any clinically relevant degree. Nonetheless, caution should be exercised when oral medicinal products are co-administered.

4.6 Pregnancy and Lactation

Pregnancy

There are limited data on semaglutide use in pregnant women to inform a medicinal-product-associated risk of adverse developmental outcomes. There are clinical considerations regarding the risks of poorly controlled diabetes in pregnancy. Based on animal reproduction studies, there may be potential risks to the foetus from exposure to semaglutide during pregnancy. Semaglutide injection should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

4.7 Effects on ability to drive and use machines

Not known.

4.8 Undesirable effects

Inflammation of your pancreas (pancreatitis). Stop using SEMAGLUTIDE INJECTION and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without vomiting. You may feel the pain from your abdomen to your back.

- Changes in vision. Tell your healthcare provider if you have changes in vision during treatment with SEMAGLUTIDE INJECTION.
- Low blood sugar (hypoglycemia). Your risk for getting low blood sugar may be higher if you use SEMAGLUTIDE INJECTION with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin. Signs and symptoms of low blood sugar may include:

o dizziness or light-headedness o blurred vision
o anxiety, irritability, or mood changes
o sweating o slurred speech
o hunger
o confusion or drowsiness
o shakiness o weakness
o headache
o fast heartbeat o feeling jittery

- K**idney problems (kidney failure).** In people who have kidney problems, diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration) which may cause kidney problems to get worse. It is important for you to drink fluids to help reduce your chance of dehydration.

Serious allergic reactions. Stop using SEMAGLUTIDE INJECTION and get medical help right away, if you have any symptoms of a serious allergic reaction including itching, rash, or difficulty breathing

Reporting of suspected adverse reactions

Healthcare professionals are asked to report any suspected adverse reactions via the Pharmacy and Poisons Board, Pharmacovigilance Electronic Reporting System (PvERS): https://pv.pharmacyboardkenya.org

4.9 Overdose

In the event of overdose, appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms. A prolonged period of observation and treatment for these symptoms may

be necessary, taking into account the long half-life of semaglutide of approximately one week.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: drugs used in diabetes, glucagon-like peptide-1 (GLP-1) analogues. ATC code: A10BJ06.

Fasting and postprandial glucose

Semaglutide reduces fasting and postprandial glucose concentrations. In patients with type 2 diabetes, treatment with semaglutide 1 mg resulted in reductions in glucose, in terms of absolute change from baseline and relative reduction compared with placebo, of 29 mg/dL (22%) for fasting glucose, 74 mg/dL (36%) for 2-hour postprandial glucose, and 30 mg/dL (22%) for mean 24-hour glucose concentration.

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5.2 Pharmacokinetic properties

Absorption

The absolute bioavailability of semaglutide is 89%. Maximum concentration is reached 1 to 3 days post-dose. Similar exposure is achieved with subcutaneous administration in the abdomen, thigh or upper arm.

Distribution

The mean apparent volume of distribution following subcutaneous administration in patients with type 2 diabetes is approximately 12.5 L. Semaglutide is extensively bound to plasma albumin (> 99%).

Biotransformation

The primary route of elimination is metabolism following proteolytic cleavage of the peptide backbone and sequential beta-oxidation of the fatty acid side chain.

Elimination

The apparent clearance in patients with type 2 diabetes is approximately 0.05 L/h. With an elimination half-life of approximately one week, semaglutide will be present in the circulation for about 5 weeks after the last dose. The primary excretion routes of semaglutide-related material are via the urine and faeces; approximately 3% of the dose is excreted in the urine as intact semaglutide.

5.3 Preclinical safety data

No data available.

6. Pharmaceutical Particulars

6.1 List of Excipients

Disodium phosphate dihydrate
Propylene glycol
Phenol
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Water for injections

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

6.3 Shelf-Life

24 months from the date of manufacture.

6.4 Special Precautions for storage

Store below 2 – 8°C

6.5 Nature and Content of container

1.5ml glass cartridge type1 closed at one end with chlorobutyll rubber plunger at other end with aluminium cap with rubber disk is used as primary packaging material for packing of SEMAGLUTIDE INJECTION (0.50 mg/Dose). One PFS is packed in a carton along with pack insert.

6.6 Special precautions for disposal and other handling

7. Marketing Authorization Holder

Ziska Pharmaceuticals Ltd.
Green City Edge (3rd floor), 89 Kakrail C/A, Dhaka-1000, Bangladesh.

8. Marketing Authorization Number

H2025/CTD11508/25179

9. Date of first authorization/renewal of the authorization

2025 January 20

10. Date of revision of the text

2025 January 20