SUMMARY OF PRODUCTS CHARACTERISTICS

1. Name of the Medicinal Product

SEMAGLO 0.25 INJECTION

2. Qualitative and Quantitative Composition

01 pre fill contains 0.25 mg Semaglutide in 0.188ml in solution.
Each dose contains 0.25 mg of Semaglutide in 0.188ml solution.
For full list of excipients see section 6.1

3. Pharmaceutical Form

Solution for Injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

SEMAGLUTIDE INJECTION is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Limitations of Use

SEMAGLUTIDE INJECTION is not recommended as a first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans.

SEMAGLUTIDE INJECTION has not been studied in patients with a history of pancreatitis.

Consider other antidiabetic therapies in patients with a history of pancreatitis.

SEMAGLUTIDE INJECTION is not a substitute for insulin. SEMAGLUTIDE INJECTION 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

Recommended Dosage

Start SEMAGLUTIDE INJECTION 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 glycemic control.

After 4 weeks on the 0.25 mg dose, increase the dosage to 0.5 mg once weekly.

If additional glycemic 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.

Administer SEMAGLUTIDE INJECTION once weekly, on the same day each week, at any time of the day, with or without meals.

The day of weekly administration can be changed if necessary as long as the time between two doses is at least 2 days (>48 hours).

Dosage and strengths:

Injection: 2 mg/1.5 mL (1.34 mg/mL) of semaglutide as a clear, colorless solution available in:

Pre-filled, disposable, single-patient-use pen that delivers 0.25 mg (for treatment initiation) or 0.5 mg (for maintenance treatment) per injection

Pre-filled, disposable, single-patient-use pen that delivers 1 mg (for maintenance treatment) per injection.

4.3 Contraindications

SEMAGLUTIDE INJECTION 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).

Known hypersensitivity to semaglutide or to any of the product components

4.4 Special warning and special precaution for use:

Risk of Thyroid C-Cell Tumors

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

Pancreatitis

In glycemic control trials, acute pancreatitis was confirmed by adjudication in 7 SEMAGLUTIDE INJECTIONtreated patients (0.3 cases per 100 patient years) versus 3 in comparator-treated patients (0.2 cases per 100 patient years). One case of chronic pancreatitis was confirmed in an SEMAGLUTIDE INJECTION-treated patient. In a 2-year trial, acute pancreatitis was confirmed by adjudication in 8 SEMAGLUTIDE INJECTION-treated patients (0.27 cases per 100 patient years) and 10 placebotreated 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 INJECTION (3.0%) compared to placebo (1.8%). The absolute risk increase for diabetic retinopathy complications was larger among patients with a history of diabetic retinopathy at baseline (SEMAGLUTIDE INJECTION 8.2%, placebo 5.2%) than among patients without a known history of diabetic retinopathy (SEMAGLUTIDE INJECTION 0.7%, placebo 0.4%).

4.5 Interaction with other medicines and other forms of interaction

The risk of hypoglycemia is increased when SEMAGLUTIDE INJECTION is used in combination with insulin secretagogues (e.g., sulfonylureas) or insulin. The risk of

hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogues) or insulin.

Oral Medications

SEMAGLUTIDE INJECTION causes a delay of gastric emptying, and thereby has the potential to impact the absorption of concomitantly administered oral medications. In clinical pharmacology trials, semaglutide did not affect the absorption of orally administered medications to any clinically relevant degree. Nonetheless, caution should be exercised when oral medications are concomitantly administered with SEMAGLUTIDE INJECTION.

4.6 Pregnancy and Lactation

Pregnancy:

Risk Summary

There are limited data with semaglutide use in pregnant women to inform a drug-associated risk for adverse developmental outcomes. There are clinical considerations regarding the risks of poorly controlled diabetes in pregnancy (see Clinical Considerations). Based on animal reproduction studies, there may be potential risks to the fetus from exposure to semaglutide during pregnancy. SEMAGLUTIDE INJECTION should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

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.

- C**hanges 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 visiono anxiety, irritability, or mood changes

o sweating o slurred speecho 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.

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 INJECTION of approximately 1 week.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Blood glucose lowering drugs, ATC code: A01B

Semaglutide lowers fasting and postprandial blood glucose and reduces body weight. All pharmacodynamic evaluations were performed after 12 weeks of treatment (including dose escalation) at steady state with semaglutide 1 mg.
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 to 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

5.2 Pharmacokinetic properties

Absorption

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

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

The apparent clearance of semaglutide in patients with type 2 diabetes is approximately 0.05 L/h. With an elimination half-life of approximately 1 week, semaglutide will be present in the circulation for about 5 weeks after the last dose.
Metabolism

The primary route of elimination for semaglutide is metabolism following proteolytic cleavage of the peptide backbone and sequential beta-oxidation of the fatty acid sidechain.
Excretion

The primary excretion routes of semaglutide-related material is via the urine and feces. 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,

PEG,

Phenol,

Sodium hydroxide,
Hydrochloric acid and
water for injection.

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 manufacturing.

6.4 Special precautions for storage:

Store below 2 - 8°C.

6.5 Nature and contents 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 SEMAGLO 0.25 INJECTION. One PFS is packed in a carton along with pack insert.

7. Marketing authorisation holder Ziska Pharmaceuticals Ltd.
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8. Marketing authorisation number(s)

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10. Date of revision of the text

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