# Semaglo OB

Semaglutide INN

**Composition**

**Semaglo OB 0.25 mg injection:** Each pre-filled syringe contains Semaglutide INN 0.25 mg in 0.50 ml solution for injection.
**Semaglo OB 0.50 mg injection:** Each pre-filled syringe contains Semaglutide INN 0.50 mg in 0.50 ml solution for injection.
**Semaglo OB 1 mg injection:** Each pre-filled syringe contains Semaglutide INN 1 mg in 0.50 ml solution for injection.
**Semaglo OB 1.7 mg injection:** Each pre-filled syringe contains Semaglutide INN 1.7 mg in 0.75 ml solution for injection.
**Semaglo OB 2.4 mg injection:** Each pre-filled syringe contains Semaglutide INN 2.4 mg in 0.75 ml solution for injection.

**Description**

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.

**Indication**

An adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adult patients 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).

**Dosage & Administration**

The starting dose is 0.25 mg Semaglutide once weekly for 4 weeks subcutaneously. Then patient should follow the dose escalation schedule given below.

**Dose Escalation Schedule**

| Weeks | Weekly Dose | |
|---|---|---|
| 1 through 4 | 0.25 mg | Dose Escalation |
| 5 through 8 | 0.50 mg | |
| 9 through 12 | 1 mg | |
| 13 through 16 | 1.7 mg | |
| Week 17 and onwards | 1.7 mg / 2.4 mg | Maintenance Dose |

If patients do not tolerate a dose during dose escalation, consider delaying dose escalation for 4 weeks. If patients do not tolerate the maintenance dose 2.4 mg , the dose can be temporarily decreased to 1.7 mg once weekly for maximum 4 weeks. After 4 weeks increase the dose to 2.4 mg. Weekly doses higher than 2.4 mg is not recommended. 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 2 days (>48 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 Semglutide is added to existing therapy of sulfonylurea or insulin, a reduction in the dose of sulfonylurea or insulin should be considered to reduse the risk of hypoglycemia.

**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 regularly scheduled day. In each case, patients can then resume their regular once weekly dosing schedule.

**Contraindications**

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 restart if pancreatitis is confirmed. Diabetic Retinopathy: Patient with diabetic retinopathy should be monitored.

**Adverse Reactions**

Sometimes hypoglycemia can occur when used insulin or sulfonylurea. The most frequent adverse reactions are gastrointestinal disorder, nausea, diarrhea, vomiting, abdominal pain and constipation.

**Drug Interaction**

Semaglutide delays gastric emptying and has the potential to impact the rate of absorption of concomitantly administered oral medicinal products.

**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. Caution should be exercised when treating these patients with Semaglutide.
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.

**Overdose**

Overdose of up to 4 mg in a single dose and up to 4 mg in a week have been reported in clinical trials. The most commonly reported adverse reaction was nausea. There is no specific antidote for overdose with Semaglutide. In the event of overdose appropriate supportive treatment should be initiated according to the patients clinical sign and symptoms.

**Storage**

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

**Packaging**

**Semaglo OB 0.25 mg Injection:** Each box contains 1 pre-filled syringe of Semaglutide 0.25 mg injection.
**Semaglo OB 0.50 mg Injection:** Each box contains 1 pre-filled syringe of Semaglutide 0.50 mg injection.
**Semaglo OB 1 mg Injection:** Each box contains 1 pre-filled syringe of Semaglutide 1 mg injection.
**Semaglo OB 1.7 mg Injection:** Each box contains 1 pre-filled syringe of Semaglutide 1.7 mg injection.
**Semaglo OB 2.4 mg Injection:** Each box contains 1 pre-filled syringe of Semaglutide 2.4 mg injection.

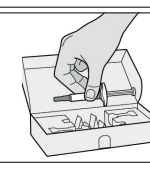
*Manufactured by*

ZISKA PHARMA

**Ziska Pharmaceuticals Ltd.**
Kaliakoir, Gazipur, Bangladesh

## Instructions for patient administration

1

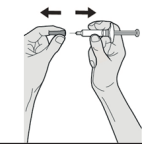


Remove Semaglo OB pre-filled syringe from the carton by holding the middle of the syringe body.

2

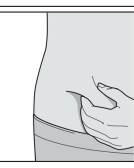
Clean the injection site with an alcohol pad. Let your skin dry before injecting.

3



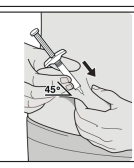
Hold the syringe in the middle and pull off the needle cap.

4



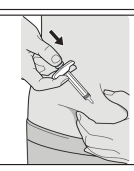
Pinch a fold of skin at the injection site. The figure above shows an example of pinching a fold of skin.

5



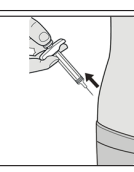

Insert the needle into the fold of the skin at about a 45º angle.

6



Relax the site. Push the plunger rod down slowly and steadily as far as it will go until the syringe is empty.

7



Pull the needle out of the skin at the same angle it was inserted. Throw away the syringe with the needle in a safe place.

8

Administer subcutaneously to the abdomen, thigh or upper arm. Choose a different site each time you inject.

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