

Fitaro™

Semaglutide Injection

Presentation

Fitaro™ 0.25 mg injection: Each pre-filled syringe contains Semaglutide INN 0.25 mg in 0.5 ml solution for injection.
Fitaro™ 0.50 mg injection: Each pre-filled syringe contains Semaglutide INN 0.50 mg in 0.5 ml solution for injection.
Fitaro™ 1 mg injection: Each pre-filled syringe contains Semaglutide INN 1 mg in 0.5 ml solution for injection.
Fitaro™ 1.7 mg injection: Each pre-filled syringe contains Semaglutide INN 1.7 mg in 0.75 ml solution for injection.
Fitaro™ 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 human GLP-1. Semaglutide acts as a GLP-1 receptor agonist that selectively binds to and activates the GLP-1 receptor. GLP-1 is a physiological regulator of appetite and caloric intake. It is also present in several areas of brain that involved in appetite regulation. Semaglutide lowers body weight through decreased caloric intake and by an overall reduced appetite. It also stimulates insulin secretion and reduces glucagon secretion in a glucose dependent manner.

Indications

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 and Administration

The starting dose is 0.25 mg Semaglutide once weekly for 4 weeks subcutaneously. Then in 4 weeks intervals dose should be increased until a dose of 2.4 mg is reached. 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 | 0.5 mg | |
| 9 through 12 | 1 mg | |
| 13 through 16 | 1.7 mg | |
| Week 17 and onwards | 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. 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.

Missed dose

If one dose is missed and the next scheduled dose is more than 2 days away (48 hours), administer Semaglutide as soon as possible. If one dose is missed and the next scheduled dose is less than 2 days away (48 hours), do not administer the dose. Resume dosing on the regular scheduled day of the week.

Contraindications

Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia Syndrome type 2. Hypersensitivity to the active substance or to any of the excipients.

Warnings & Precautions

Pancreatitis: Semaglutide should be discontinued promptly if pancreatitis is suspected and it should not be restart if pancreatitis is confirmed.

Acute Gallbladder Disease: If cholelithiasis is suspected, gallbladder studies and clinical follow-up are indicated.

Hypoglycemia: Concomitant use with an insulin secretagogues or insulin may increase the risk of hypoglycemia. Reducing the dose of insulin secretagogue or insulin may be necessary.

Diabetic Retinopathy: Patient with diabetic retinopathy should be monitored.

Heart Rate: Heart rate should be monitor at regular intervals.

Suicidal behavior and Ideation: Monitor should be done for depression or suicidal thoughts. If symptoms develop, semaglutide should be discontinued.

Adverse Reaction

The most common adverse reactions are: nausea, diarrhea, vomiting, constipation, abdominal pain, headache, fatigue, dyspepsia, dizziness, abdominal distension, eructation, hypoglycemia in patients with type 2 diabetes, flatulence, gastroenteritis, and gastroesophageal reflux disease.

Drug interaction

Semaglutide lowers blood glucose and can cause hypoglycemia. The risk of hypoglycemia is increased when it is used in combination with insulin secretagogues (sulfonylureas) or insulin. So when initiating Semaglutide, the dose of concomitantly administered insulin secretagogue (sulfonylureas) or insulin should be reduce.

Special 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.

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. No data are available.

Overdose

The most commonly reported adverse reaction was nausea, vomiting and hypoglycemia. All patients recovered without complications. In the event of overdose appropriate supportive treatment should be initiated according to the patients clinical sign and symptoms.

Storage

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

Commercial Pack

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Manufactured by

 **Incepta Pharmaceuticals Ltd**

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