

Composition : **Mysema-7** : Each Tablet contains Semaglutide INN 7mg.

Pharmacology : Semaglutide is a GLP-1 analogue with 94% sequence homology to human GLP-1. Semaglutide acts as a GLP-1 receptor against that selectively binds to and activates the GLP-1 receptor, the target for native GLP-1. GLP-1 is a physiological hormone that has multiple actions on glucose, mediated by the GLP-1 receptors. The principal mechanism of protraction resulting in the long half-life of Semaglutide is albumin binding, which results in decreased renal clearance and protection from metabolic degradation. Furthermore, Semaglutide is stabilized against degradation by the DPP-4 enzyme. Semaglutide reduces blood glucose through a mechanism where it stimulates insulin secretion and lowers glucagon secretion, both in a glucose-dependant manner. Thus, when blood glucose is high, insulin secretion is stimulated and glucagon secretion is inhibited. The mechanism of blood glucose lowering also involves a minor delay in gastric emptying in the early postprandial phase.

Indications : Semaglutide is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **Important Administrative Instruction:**

patients should be instructed to take semaglutide at least 30 minutes before the first food, beverage, or other oral medications of the day with no more than 4 ounces of plain water only. Waiting less than 30 minutes, or taking with food, beverages (other than plain water) or other oral medications will lessen the effect of semaglutide. Waiting more than 30 minutes to eat may increase the absorption of semaglutide.

Dosage & Administration : Semaglutide should be started with 3 mg once daily for 30 days. The 3mg dose is intended for treatment initiation and is not effective for glycemic control. After 30 days on the 3 mg dose, increase the dose to 7 mg once daily. Dose may be increased to 14 mg once daily if additional glycemic control is needed after at least 30 days on the 7 mg dose. Taking two 7 mg tablets to achieve a 14 mg dose is not recommended. If a dose is missed, the missed dose should be skipped, and the next dose should be taken the following day. Or, as directed by the registered physician.

Contraindication : Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2. Known hypersensitivity to semaglutide or any of the components in this preparation.

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

Mysema-7 Tablet



Diabetic Retinopathy: Patient with diabetic retinopathy should be monitored. **Hypoglycemia:** When Semaglutide is used with an insulin secretagogue or insulin, consider lowering the dose of the secretagogue or insulin to reduce the risk of hypoglycemia. **Acute Kidney Injury:** Monitor renal function in patients with renal impairment reporting severe adverse gastrointestinal reactions. **Hypersensitivity Reactions:** Discontinue Semaglutide if suspected and promptly seek medical advice.

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

Use in Pregnancy and Lactation : There are limited data with semaglutide use in pregnant women. Semaglutide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. There are no data on the presence of Semaglutide in human milk, the effects on the breastfed infant, or the effects on milk production. Discontinue Semaglutide in women at least 2 months before a planned pregnancy due to the long washout period for Semaglutide.

Use in Child : The safety and efficacy of Semaglutide in children and adolescents below 18 years have not yet been established.

Drug Interactions : Oral Medications: Semaglutide delays gastric emptying. When coadministering oral medications instruct patients to closely follow semaglutide administration instructions. Consider increased clinical or laboratory monitoring for medications that have a narrow therapeutic index or that require clinical monitoring.

Overdose : 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 below 30°C in a dry place. Do not freeze. Keep out of the reach of children.

Packing : Mysema-7 : Each box contains 60's tablets in a blister pack.