Semaxen

Semaglutide INN

Everest

COMPOSITION

Semaxen 3 Tablet: Each film coated tablet contains Semaglutide INN 3 mg.
Semaxen 7 Tablet: Each film coated tablet contains Semaglutide INN 7 mg.

PHARMACOLOGY

Semaglutide acts as a GLP-1 receptor agonist that selectively binds to and activates the GLP-1 receptor. The GLP-1 receptor is the target for native GLP-1, an endogenous incretin hormone that potentiates glucose-dependent insulin secretion from the pancreatic beta cells. Unlike native GLP-1, Semaglutide has a half-life of approximately one week. This long plasma half-life is based on binding to albumin, which reduces renal clearance, and increased enzymatic stability towards the dipeptidyl peptidase (DPP-IV) enzyme. Semaglutide action is mediated via a specific interaction with GLP-1 receptors, leading to an increase in cyclic adenosine monophosphate (cAMP). Semaglutide stimulates insulin secretion in a glucose-dependent manner. Simultaneously, Semaglutide lowers glucagon secretion, also in a glucose-dependent 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 delay in gastric emptying.

INDICATION

Semaxen is indicated:

- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus:
- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications;
- in combination with other medicinal products for the treatment of diabetes.

DOSAGE AND ADMINISTRATION

- The recommended starting dose of Semaxen is 3 mg once daily orally.
- After 30 days, the dose should be increased to a maintenance dose of 7 mg once daily.
- The dosage may be increased to 14 mg once daily if additional glycemic control is needed after at least 30 days on the 7 mg dosage.

CONTRAINDICATION

Semaxen is contraindicated in patients who are hypersensitive to Semaxen or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. Semaxen is contraindicated in patients who have a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Semaxen should not be used during pregnancy or breastfeeding.

WARNING AND PRECAUTION

Should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Risk of Thyroid C-Cell Tumours. Patients should be advised to take precautions to avoid hypoglycemia while driving and using machines. Semaglutide causes an increase in heart rate. Caution should be observed in patients who have cardiac conditions that might be worsened by an increase in heart rate, such as tachyarrhythmias. Patients treated with semaglutide in combination with an insulin secretagogue (e.g., sulfonylureas) or insulin may have an increased risk of hypoglycemia. The risk of hypoglycemia may be lowered by reducing the dose of the secretagogue or insulin when initiating treatment with Semaxen.

SIDE EFFECTS

Common side effects:
vomiting, stomach upset or indigestion inflamed stomach, reflux or heartburn or GERD, stomac pain, bloating of the stomach, constipation, change in the way food or drink tastes, tiredness, less appetite, gas (flatulence), increase of pancreatic enzymes (such as lipase and amylase).

Rare side effects:
serious allergic reactions (anaphylactic reactions). You should seek immediate medical help and inform your doctor straight away if you get symptoms such as breathing problems, swelling of face and throat, wheezing, fast heartbeat, pale and cold skin, feeling dizzy or weak.

USE IN PREGNANCY AND LACTATION

Pregnancy:
The extent of exposure in pregnancy during clinical trials was very limited and there are no adequate and well-controlled studies of Semaglutide in pregnant women. Therefore, Semaxen should not be used during pregnancy. If a patient wishes to become pregnant, or pregnancy occurs, Semaxen should be discontinued. Semaxen should be discontinued at least 2 months before a planned pregnancy due to the long half-life of Semaglutide.

Lactation:
There are no data on the presence of semaglutide in human milk, the effects on the breastfed infant, or the effects on milk production. Because of the unknown potential for serious adverse reactions in the breastfed infant due to the possible accumulation of salcaprozate sodium (SNAC), an absorption enhancer in Semaxen, from breastfeeding and because there are alternative formulations of semaglutide that can be used during lactation, advise patients that breastfeeding is not recommended during treatment with Semaxen. Discontinue Semaxen in women at least 2 months before a planned pregnancy due to the long washout period for semaglutide.

USE IN PEDIATRIC POPULATION

The safety and efficacy of Semaxen in children and adolescents below 18 years have not been studied.

USE IN GERIATRIC POPULATION

No overall differences in safety or effectiveness for Semaglutide have been observed between patients 65 years of age and older and younger adult patients.

DRUG INTERACTION

With medicine: Semaglutide delays gastric emptying which may influence the absorption of other oral medications. Trials were conducted to study the potential effect of Semaglutide on the absorption of oral medicinal products taken with Semaglutide administered orally at steadystate exposure.
With food & others: Concomitant intake of food reduces the exposure of semaglutide.

OVERDOSE

If Semaxen is overdosed, then patient should talk to doctor. Patient may have side effects such as feeling sick (nausea).

STORAGE

Store below 30°C, in a cool and dry place. Keep away from light. Keep all the medicine out of the reach of children.

HOW SUPPLIED

Semaxen 3 Tablet: Each HDPE container/blister contains 10 film coated tablets, a silica gel desiccant and polyester coil with a child-resistant closure.
Semaxen 7 Tablet: Each HDPE container/blister contains 10 film coated tablets, a silica gel desiccant and polyester coil with a child-resistant closure.

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Manufactured by
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