

Ozempic® Abbreviated Product Information

Therapeutic indication:

Ozempic® is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise

- **as monotherapy when metformin is considered inappropriate due to intolerance or contraindications**
- **in addition to other medicinal products for the treatment of diabetes.**

Contraindication: Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of the full Israeli physician leaflet.

Special warnings:

Semaglutide should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Semaglutide is not a substitute for insulin.

Diabetic ketoacidosis:

Has been reported in insulin-dependent patients whom had rapid discontinuation or dose reduction of insulin when treatment with a GLP-1 receptor agonist is started.

Heart failure:

There is no experience in patients with congestive heart failure NYHA class IV and semaglutide is therefore not recommended in these patients.

Aspiration in association with general anaesthesia or deep sedation:

Cases of pulmonary aspiration have been reported in patients receiving GLP-1 RA undergoing general anaesthesia or deep sedation. Therefore, the increased risk of residual gastric content due to delayed gastric emptying should be considered prior to performing procedures with general anaesthesia or deep sedation.

Gastrointestinal effects and dehydration:

Use of GLP-1 RA may be associated with gastrointestinal adverse reactions. This should be considered when treating patients with impaired renal function as nausea, vomiting, and diarrhoea may cause dehydration which in rare cases can lead to a deterioration of renal function. Patients treated with semaglutide should be advised of the potential risk of dehydration in relation to gastrointestinal side effects and take precautions to avoid fluid depletion.

Acute pancreatitis:

Acute pancreatitis has been observed with the use of GLP-1 RA. Patients should be informed of the characteristic symptoms of acute pancreatitis. If pancreatitis is suspected, semaglutide should be discontinued; if confirmed, semaglutide should not be restarted. Caution should be exercised in patients with a history of pancreatitis.

Hypoglycaemia:

Patients treated with semaglutide in combination with a sulfonylurea or insulin may have an increased risk of hypoglycaemia.

Diabetic retinopathy:

In patients with diabetic retinopathy treated with insulin and Semaglutide, an increased risk of developing diabetic retinopathy complications has been observed.

Non-arteritic anterior ischaemic optic neuropathy (NAION):

Data from epidemiological studies indicates an increased risk for NAION during treatment with semaglutide. There is no identified time interval for when NAION may develop following treatment start. A sudden loss of vision should lead to ophthalmological examination and treatment with semaglutide should be discontinued if NAION is confirmed.

Patients with gastroparesis:

Semaglutide treated patients with gastroparesis may experience more serious or severe gastrointestinal adverse events. Semaglutide should be used with caution in these patients, and semaglutide is not recommended if gastroparesis is severe.

For full list of warnings and further information please refer to full Israeli physician leaflet.

Safety profile: The most frequently reported adverse reactions during treatment with Ozempic® were:

1. Gastrointestinal disorders, including nausea and diarrhoea
2. Hypoglycaemia (when used with insulin or sulfonylurea).

For full list of adverse reactions and further information please refer to the full physician leaflet as appears in the MOH website.

Marketing registration holder: Novo Nordisk LTD, Israel

