Prescribing Information

Ozempic® ▼
semaglutide

Ozempic® 0.25 mg solution for injection in pre-filled pen
Ozempic® 0.5 mg solution for injection in pre-filled pen
Ozempic® 1 mg solution for injection in pre-filled pen

One ml of solution contains 1.34 mg of semaglutide (human glucagon-like peptide-1 (GLP-1)).

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.

For study results with respect to combinations, effects on glycaemic control and cardiovascular events, and the populations studied, see sections 4.4, 4.5 and 5.1.

Posology and administration: Administered once weekly at any time of the day, with or without meals. Injected subcutaneously in the abdomen, thigh or upper arm. Starting dose: 0.25 mg once weekly. After 4 weeks the dose should be increased to 0.5 mg once weekly. After at least 4 weeks with a dose of 0.5 mg once weekly, the dose can be increased to 1 mg once weekly to further improve glycaemic control. Children: No data available. Elderly: No dose adjustment, therapeutic experience in patients ≥75 is limited. Renal impairment: No dose adjustment is required for patients with mild, moderate or severe renal impairment. Experience in patients with severe renal impairment is limited. Not recommended for use in patients with end-stage renal disease. Hepatic impairment: No dose adjustment is required for patients with hepatic impairment. Experience with severe hepatic impairment is limited. Caution should be exercised when treating these patients with semaglutide.
Contraindications: Hypersensitivity to the active substance or to any of the excipients
Special warnings and Precautions for use: Should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Not a substitute for insulin. There is no experience in patients with congestive heart failure NYHA class IV and is therefore not recommended in these patients. Use of GLP-1 receptor agonists 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 could cause a deterioration of renal function. Acute pancreatitis has been observed with the use of GLP-1 receptor agonists. 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.
Use of semaglutide in combination with a sulfonylurea or insulin may have an increased risk of hypoglycaemia. The risk of hypoglycaemia can be lowered by reducing the dose of sulfonylurea or insulin when initiating treatment with semaglutide. In patients with diabetic retinopathy treated with insulin and semaglutide, an increased risk of developing diabetic retinopathy complications has been observed. Caution should be exercised when using semaglutide in patients with diabetic retinopathy treated with insulin. These patients should be monitored closely and treated according to clinical guidelines. Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy, but other mechanisms cannot be excluded. When semaglutide is used in combination with a sulfonylurea or insulin, patients should be advised to take precautions to avoid hypoglycaemia while driving and using machines.
Fertility, pregnancy and lactation: Women of childbearing potential are recommended to use contraception when treated with semaglutide. Should not be used during pregnancy or breast-feeding. Discontinue at least 2 months before a planned pregnancy. Effect on fertility unknown.
Undesirable effects: The Summary of Product Characteristics should be consulted in relation to other adverse reactions.
Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.
Very common (≥1/10); Hypoglycaemia when used with insulin or sulfonylurea, nausea, diarrhoea *Common: (≥1/100 to <1/10);* Hypoglycaemia when used with other OADs, decreased appetite, dizziness, diabetic retinopathy complications, vomiting, abdominal pain, abdominal distension, constipation, dyspepsia, gastritis, gastro-oesophageal reflux disease, eructation, flatulence, cholelithiasis, fatigue, increased lipase, increased amylase, weight decreased. U*ncommon: (≥1/1,000 to <1/100);* Dysgeusia, increased heart rate, injection site reactions. *Rare: (≥1/10,000 to <1/1,000)* Anaphylactic reaction.

MA numbers and Basic NHS Price:
Ozempic® 0.25 mg pre-filled pen EU/1/17/1251/002 £73.25;
Ozempic® 0.5 mg pre-filled pen EU/1/17/1251/003 £73.25;
Ozempic® 1 mg pre-filled pen EU/1/17/1251/005 £73.25
Legal Category: POM.
Further prescribing information can be obtained from: Novo Nordisk Limited, 3 City Place, Beehive Ring Road, Gatwick, West Sussex, RH6 0PA.
Marketing Authorisation Holder: Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark.

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Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse events should also be reported to Novo Nordisk Limited (Telephone Novo Nordisk Customer Care Centre 0845 6005055). Calls may be monitored for training purposes.