Prepared and updated by Global Medical Affairs Semaglutide once-weekly based on EU SmPC
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Abbreviated 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
Ozempic 2 mg solution for injection in pre-filled pen

Consult Summary of Product Characteristics before prescribing.
Presentation: Ozempic 0.25 mg & 0.5 mg solution for injection: Each pre-filled pen contains 2 mg semaglutide in 1.5 ml solution. Ozempic 1 mg solution for injection: One pre-filled pen contains 4 mg semaglutide in 3.0 ml solution. Ozempic 2 mg solution for injection: One pre-filled pen contains 8 mg semaglutide in 3.0 ml solution. **Uses:** 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. Combination therapy: in addition to other medicinal products for the treatment of diabetes. For trial results with respect to combinations, effects on glycaemic control and cardiovascular events, and the populations studied, see the full Summary of Product Characteristics. **Dosage and Administration:** The starting dose is 0.25 mg Ozempic® 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. After at least 4 weeks with a dose of 1 mg once weekly, the dose can be increased to 2 mg once weekly to further improve glycaemic control. Weekly doses higher than 2 mg are not recommended. Ozempic® is to be administered once weekly at any time of the day, with or without meals. Ozempic® is to be injected subcutaneously in the abdomen, in the thigh or in the upper arm. Ozempic® should not be administered intravenously or intramuscularly. When Ozempic® is added to existing metformin and/or thiazolidinedione therapy or to a , sodium-glucose cotransporter-2 (SGLT2) inhibitor, the current dose of these medications can be continued unchanged. Blood glucose self-monitoring is necessary to adjust the dose of sulfonylurea and insulin, particularly when Ozempic is started and insulin is reduced. A stepwise approach to insulin reduction is recommended. **Elderly:** No dose adjustment is required based on age. Therapeutic experience in patients aged ≥75 years of age 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 in patients with severe hepatic impairment is limited. Caution should be exercised when treating these patients with Ozempic®. **Paediatric population:** The safety and efficacy of Ozempic® in children and adolescents below 18 years have not yet been established. No data are available. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Special warnings and precautions for use:** Ozempic® should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Ozempic® 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. There is no experience in patients with congestive heart failure NYHA class IV and Ozempic® is therefore not recommended in these patients. The possibility of gastrointestinal adverse reactions should be considered when treating patients with impaired renal function as nausea, vomiting, and diarrhea may cause dehydration, which could cause a deterioration of renal function. Patients should be informed of the characteristic symptoms of acute pancreatitis. If pancreatitis is suspected, Ozempic® should be discontinued; if confirmed, Ozempic® should not be restarted. Caution should be exercised in patients with a history of pancreatitis. Patients treated with Ozempic® in combination with a sulfonylurea or insulin may have an increased risk of hypoglycaemia. Consider reducing the dose of sulfonylurea or insulin when initiating treatment with Ozempic®. In patients with diabetic retinopathy treated with insulin and Ozempic®, an increased risk of developing diabetic retinopathy complications has been observed. Caution should be exercised when using Ozempic® 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. There is no experience with semaglutide 2 mg in patients with type 2 diabetes with uncontrolled or potentially unstable diabetic retinopathy and semaglutide 2 mg is therefore not recommended in these patients. **Interactions:** Ozempic® delays gastric emptying and has the potential to impact the rate of absorption of concomitantly administered oral medicinal products. Ozempic® should be used with caution in patients receiving oral medicinal products that require rapid gastrointestinal absorption. No dose adjustment of paracetamol, oral contraceptives (ethinylestradiol and levonorgestrel), atorvastatin, digoxin or metformin is necessary when administered with Ozempic®. Upon initiation of semaglutide treatment in patients on warfarin or other coumarin derivatives, frequent monitoring of INR is recommended since cases of decreased INR have been reported during concomitant use of acenocoumarol and semaglutide.
For further details of these interaction studies, please see the Summary of Product Characteristics. **Pregnancy and lactation:** Ozempic® should not be used during pregnancy. If a patient wishes to become pregnant, or pregnancy occurs during treatment, Ozempic® should be discontinued. Ozempic® should not be used during breast-feeding. Effect of Ozempic® on fertility in humans is unknown. **Driving or using machines:** When Ozempic® is used in combination with a sulfonylurea or insulin, patients should be advised to take precautions to avoid hypoglycaemia while driving and using machines. **Undesirable Effects:** The most frequently reported adverse reactions with Ozempic® in clinical trials were gastrointestinal disorders, including nausea, diarrhoea, and vomiting. Adverse reactions by system organ class and absolute frequencies identified in all phase 3a trials listed here as *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-esophageal reflux disease, eructation, flatulence, cholelithiasis, fatigue, increased lipase, increased amylase, weight,decreased; *Uncommon (≥1/1,000 to <1/100)*: hypersensitivity, dysgeusia, increased heart rate, acute pancreatitis, delayed gastric emptying injection site reactions; *Rare (≥1/10,000 to <1/1,000)*: anaphylactic reaction; Not known (cannot be estimated from available data): angioedema, intestinal obstruction For further details of these side-effects, please see the Summary of Product Characteristics, which is available at www.novonordisk.com.
Marketing authorisation number:
Ozempic® 0.25 mg in pre-filled pen 1.5 ml (1.34 mg/ml): EU/1/17/1251/002
Ozempic® 0.5 mg in pre-filled pen 1.5 ml (1.34 mg/ml): EU/1/17/1251/003
Ozempic® 1 mg in pre-filled pen 3 ml (1.34 mg/ml): EU/1/17/1251/005
Ozempic® 2 mg in pre-filled pen 3 ml (2.68 mg/ml): EU/1/17/1251/010
Legal category: Prescription-only medicine (POM) **Marketing authorisation holder:** Novo Nordisk A/S Novo Allé DK-2880 Bagsværd Denmark. **Date of review of abbreviated prescribing information:** April 2024. Summary of Product Characteristics can be obtained from Novo Nordisk A/S.**Document Number: HQ24OZM00043**