This Abbreviated Prescribing Information (API) reflects the SmPC effective of 2024-01-25 [based on commission date ☒ /27 days after positive opinion if yearly commission date ☐]
Were changes done to this API as a result of the SmPC change above? YES ☒ NO ☐

Prepared and updated by Global Medical Affairs, based on EU SmPC (Latest version, post-EC approval)
Abbreviated prescribing information
Wegovy® (semaglutide injection)
The Summary of Product Characteristics (SmPC) is available at Novo Nordisk A/S.

Presentation: Wegovy® 0.25 mg, 0.5 mg, 1mg solution for injection; Each single-dose pre-filled pen contains 0.25 mg, 0.5mg & 1mg semaglutide* in 0.5 mL solution. Wegovy® 1.7mg & 2.4mg solution for injection; Each single-dose pre-filled pen contains 1.7mg & 2.4mg semaglutide* in 0.75 mL solution. Wegovy® 0.25 mg & 0.5mg FlexTouch solution for injection; Each pre-filled pen contains 1 mg & 2mg semaglutide* in 1.5 mL solution. Wegovy® 1mg, 1.7mg & 2.4mg FlexTouch solution for injection; Each pre-filled pen contains 4 mg, 6.8mg & 9.6mg semaglutide* in 3 mL solution.
Indications: Wegovy® is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of ≥30 kg/m2 (obesity), or ≥27 kg/m^2 to <30 kg/m^2 (overweight) in the presence of at least one weight-related comorbidity e.g. dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia, obstructive sleep apnoea or cardiovascular disease. Wegovy® is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adolescents ages 12 years and above with obesity (BMI ≥95th percentile, as defined on sex- and age-specific BMI growth charts (CDC.gov)) and body weight above 60 kg. Treatment with Wegovy® should be discontinued and re-evaluated if adolescent patients have not reduced their BMI by at least 5% after 12 weeks on the 2.4 mg or maximum tolerated dose. **Dosage and administration**: Adults: maintenance dose of semaglutide 2.4 mg once-weekly is reached by starting with a dose of 0.25 mg. To reduce likelihood of gastrointestinal symptoms, dose should be escalated over a 16-week period to a maintenance dose of 2.4 mg once weekly. In case of significant gastrointestinal symptoms, consider delaying dose escalation or lowering to previous dose until symptoms have improved. Adolescents (12 years and above): same dose escalation schedule as for adults should be applied. The dose should be increased until 2.4 mg (maintenance dose) or maximum tolerated dose has been reached. In adults & adolescents, weekly doses higher than 2.4 mg are not recommended. Wegovy® is administered once weekly at any time of the day, with or without meals. It is to be injected subcutaneously in the abdomen, thigh or upper arm. The injection site can be changed. It should not be administered intravenously or intramuscularly. The day of weekly administration can be changed, if necessary, as long as the time between two doses is at least 3 days (>72 hours). After selecting a new dosing day, once-weekly dosing should be continued. When initiating Wegovy® in patients with type 2 diabetes, consider reducing the dose of concomitantly administered insulin or insulin secretagogues (such as sulfonylureas) to reduce the risk of hypoglycaemia. The safety and efficacy of Wegovy® in children below 12 years of age have not been established. **Contraindications:** Hypersensitivity to active substance or to any of the excipients**. Special warnings and precautions:** Dehydration: Use of GLP-1 receptor agonists may be associated with gastrointestinal adverse reactions that can cause dehydration, which in rare cases can lead to a deterioration of renal function. Patients 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 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. In the absence of other signs and symptoms of acute pancreatitis, elevations in pancreatic enzymes alone are not predictive of acute pancreatitis. Patients with type 2 diabetes: Semaglutide should not be used as a substitute for insulin in patients with type 2 diabetes. Semaglutide should not be used in combination with other GLP-1 receptor agonist products. It has not been evaluated and an increased risk of adverse reactions related to overdose is considered likely. Hypoglycaemia in patients with type 2 diabetes: Patients with type 2 diabetes treated with 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 a GLP-1 receptor agonist. The addition of Wegovy® in patients treated with insulin has not been evaluated. Diabetic retinopathy in patients with type 2 diabetes: In patients with diabetic retinopathy treated with semaglutide, an increased risk of developing diabetic retinopathy complications has been observed. Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy, but other mechanisms cannot be excluded. Patients with diabetic retinopathy using semaglutide should be monitored closely and treated according to clinical guidelines. There is no experience with Wegovy® in patients with type 2 diabetes with uncontrolled or potentially unstable diabetic retinopathy. In these patients, treatment with Wegovy® is not recommended. The safety and efficacy of Wegovy® have not been investigated in patients: treated with other products for weight management, with type 1 diabetes, severe renal impairment, with severe hepatic impairment, congestive heart failure New York Heart Association (NYHA) class IV. Use in these patients is not recommended. There is limited experience with Wegovy® in patients: aged 75 years or more, with mild or moderate hepatic impairment, inflammatory bowel disease, diabetic gastroparesis. Use with caution in these patients. **Pregnancy and lactation:** Semaglutide should not be used in women who are pregnant, who wish to become pregnant, or who are breastfeeding. **Effects on ability to drive & use machines:** Semaglutide has no or negligible influence on the ability to drive or use machines. However, dizziness can be experienced mainly during dose escalation period. Driving or use of machines should be done cautiously if dizziness occurs. **Undesirable effects:** In patients treated with Wegovy®, very common adverse reactions: include headache, vomiting, diarrhoea, constipation, nausea, abdominal pain, fatigue. Common adverse reactions: include hypoglycaemia in patients with type 2 diabetes, dizziness, dysgeusia, diabetic retinopathy in patients with type 2 diabetes, gastritis, gastrooesophageal reflux disease, dyspepsia, eructation, flatulence, abdominal distension, cholelithiasis, hair loss, injection site reactions. Uncommon adverse reactions: include hypotension, orthostatic hypotension, increased heart ratea, acute pancreatitis, delayed gastric emptying, increased amylase, increased lipase. Rare adverse reactions: include anaphylactic reaction, angioedema. Overall, the frequency, type and severity of adverse reactions in the adolescents were comparable to that observed in the adult population. Cholelithiasis was reported in 3.8% of patients treated with Wegovy® and 0% of patients treated with placebo. **Overdose:** Overdose with semaglutide may be associated with gastrointestinal disorders which could lead to dehydration. In the event of overdose the patient should be observed for clinical signs and appropriate supportive treatment initiated

Marketing authorisation numbers: EU/1/21/1608/001, EU/1/21/1608/002, EU/1/21/1608/003, EU/1/21/1608/004, EU/1/21/1608/005, EU/1/21/1608/006, EU/1/21/1608/007, EU/1/21/1608/008, EU/1/21/1608/009, EU/1/21/1608/010, EU/1/21/1608/011. **Date of preparation: Mar 2024**