The Summary of Product Characteristics (SmPC) is based on the EU SmPC as of April 2021. Registration conditions differ internationally. Always refer to the full local SmPC before prescribing. Saxenda® is registered in EU, USA, Canada, Latin America, Middle East and Asia.

Abbreviated prescribing information
Saxenda® (liraglutide injection)
The Summary of Product Characteristics (SmPC) is available novonordisk.com.

Presentation: Prefilled, disposable pen containing 18 mg of liraglutide in 3 mL of solution. **Indications:** Saxenda® is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (BMI) of ⩾ 30 kg/m² (obese), or ⩾ 27 kg/m² to < 30 kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (prediabetes or type 2 diabetes mellitus),hypertension, dyslipidaemia or obstructive sleep apnoea. In adults, treatment with Saxenda® should be discontinued after 12 weeks on the 3.0 mg/day dose if patients have not lost at least 5% of their initial body weight. Saxenda® can be used as an adjunct to a healthy nutrition and increased physical activity for weight management in adolescent patients from the age of 12 years and above with: obesity (BMI corresponding to ⩾30 kg/m² for adults by international cut-off points) and body weight above 60 kg. In adolescents (⩾12 years), treatment with Saxenda® should be discontinued and re-evaluated if patients have not lost at least 4% of their BMI or BMI z score after 12 weeks on the 3.0 mg/day or maximum tolerated dose. **Dosage and administration:** Adults: The starting dose is 0.6 mg once daily. The dose should be increased to 3.0 mg daily in increments of 0.6 mg with at least one-week interval to improve gastro-intestinal tolerability. If escalation to the next dose step is not tolerated for two consecutive weeks, consider discontinuing treatment. Adolescents: For adolescents from the age of 12 to below 18 years old a similar dose escalation schedule as for adults should be applied. The dose should be increased until 3.0 mg (maintenance dose) or maximum tolerated dose has been reached. Daily doses higher than 3.0 mg are not recommended. Saxenda® is administered once daily at any time, independent of meals, subcutaneously injected in the abdomen, thigh or upper arm, preferably around the same time every day. Saxenda® must not be administered intravenously or intramuscularly. When initiating Saxenda® in patients with type 2 diabetes mellitus, consider reducing the dose of concomitantly administered insulin or insulin secretagogues (such as sulfonylureas) to reduce the risk of hypoglycaemia. Blood glucose self-monitoring is necessary to adjust the dose of insulin or insulin-secretagogues. Saxenda® should not be used in combination with another Glucagon-like Peptide-1 (GLP-1) receptor agonist. The safety and efficacy of Saxenda® in children below 12 years of age has not been established.

Contraindications: Hypersensitivity to liraglutide or to any of the excipients. **Special warnings and precautions:** In patients with diabetes mellitus Saxenda® must not be used as a substitute for insulin. Diabetic ketoacidosis has been reported in insulin-dependent patients after rapid discontinuation or dose reduction of insulin. There is no experience in patients with congestive heart failure New York Heart Association (NYHA) class IV and liraglutide is therefore not recommended for use in these patients. Due to limited experience, Saxenda® is not recommended in patients with inflammatory bowel disease or diabetic gastroparesis. Saxenda® is not recommended in patients: aged 75 years or more, treated with other products for weight management, with obesity secondary to endocrinological or eating disorders or to treatment with medicinal products that may cause weight gain, with severe renal impairment, with severe hepatic impairment. Saxenda® must be used with caution in patients with mild or moderate hepatic impairment. 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, liraglutide should be discontinued; if acute pancreatitis is confirmed, liraglutide should not be restarted. In clinical trials for weight management, a higher rate of cholelithiasis and cholecystitis was observed in patients treated with liraglutide than in patients on placebo. Patients should be informed of the characteristic symptoms of cholelithiasis and cholecystitis. In clinical trials in type 2 diabetes, thyroid adverse events, such as goitre have been reported mainly in patients with pre-existing thyroid disease. Liraglutide should therefore be used with caution in patients with thyroid disease. An increase in heart rate was observed with liraglutide in clinical trials. Heart rate should be monitored at regular intervals consistent with usual clinical practice. Patients should be informed of the symptoms of increased heart rate (palpitations or feelings of a racing heartbeat while at rest). For patients who experience a clinically relevant sustained increase in resting heart rate, treatment with liraglutide should be discontinued. Patients treated with liraglutide should be advised of the potential risk of dehydration in relation to gastrointestinal side effects and take precautions to avoid fluid depletion. Episodes of clinically significant hypoglycaemia have been reported in adolescents (≥12 years) treated with liraglutide. Patients should be informed about the characteristic symptoms of hypoglycaemia and the appropriate actions. **Pregnancy and lactation:** Saxenda® should not be used in women who are pregnant, who wish to become pregnant, or who are breastfeeding. **Undesirable effects:** The most frequently reported adverse reactions in patients treated with Saxenda® are nausea, vomiting, diarrhoea and constipation. Common adverse reactions include dyspepsia, upper abdominal pain, gastritis, flatulence, abdominal distension, gastroesophageal reflux, eructation, dry mouth, dizziness, dysgeusia, insomnia, fatigue, asthenia, injection site reactions, increased lipase, increased amylase, hypoglycaemia and cholelithiasis. Uncommon adverse reactions include dehydration, tachycardia, urticaria, pancreatitis, delayed gastric emptying, cholecystitis and malaise. Rare adverse reactions include anaphylactic reaction, acute renal failure and renal impairment. Overall frequency, type, and severity of adverse reactions in adolescents with obesity

were comparable to those observed in the adult population. Vomiting occurred with a 2-fold higher frequency in adolescents compared to adults. **Overdose:** From clinical trials and marketed use overdoses have been reported up to 72 mg (24 times the recommended maintenance dose). Events reported included severe nausea, severe vomiting and severe hypoglycaemia. In the event of overdose, appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms. The patient should be observed for clinical signs of dehydration and blood glucose should be monitored.

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