Saxenda®

liraglutide injection

Abbreviated Prescribing Information Singapore: Saxenda® (Liraglutide injection) 6 mg/ml Solution for injection in pre-filled pen **Presentation**: Prefilled, disposable pen containing 18 mg of liraglutide in 3 mL of solution. 1 ml of solution contains 6 mg of liraglutide Indications: **Adults**: 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 (obesity), or ≥27 kg/m² to <30 kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (pre-diabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea. 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. The need for continued treatment should be re-evaluated annually. **Adolescents (≥12 years)**: 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: an inadequate response to reduced calorie diet and increased physical activity alone, and obesity (BMI corresponding to ≥30 kg/m2 for adults by international cut-off points) * and body weight above 60 kg. **Limitations of Use**: The safety and effectiveness of Saxenda® in paediatric patients with type 2 diabetes have not been established. 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. **Posology**: The starting dose is 0.6 mg once daily. The dose should be increased to 3.0 mg once 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. Daily doses higher than 3.0 mg are not recommended. Adolescents (≥12 years): For adolescents from the age of 12 to below 18 years old a similar dose escalation schedule as for adults should be applied (see table 2). The dose should be increased until 3.0 mg (maintenance dose) or maximum tolerated dose has been reached. **Administration**: Saxenda® is for subcutaneous injection only, administered once daily at any time, independent of meals. Saxenda® should be injected in the abdomen, thigh or upper arm, preferably around the same time every day. Saxenda® must not be administered intravenously or intramuscularly. Saxenda® should not be mixed with other injectables (e.g. insulins). Patients with type 2 diabetes mellitus receiving liraglutide in combination with a sulfonylurea may have an increased risk of hypoglycaemia. The risk of hypoglycaemia may be lowered by a reduction in the dose of sulfonylurea. Saxenda® should not be used in combination with other Glucagon-like Peptide-1 (GLP-1) receptor agonist. Blood glucose self-monitoring is necessary to adjust the dose of insulin or insulin-secretagogues. 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 clinical experience in patients with congestive heart failure New York Heart Association (NYHA) class IV and liraglutide use is not recommended for use in these patients. 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® should be used cautiously 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 suspected, discontinue liraglutide; 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. 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 in patients with pre-existing 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. Patients treated with Saxenda® should be monitored for the emergence or worsening of depression, suicidal thoughts or behaviour, and/or any unusual changes in mood or behaviour. Discontinue Saxenda® in patients who experience suicidal thoughts or behaviours. 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. Less 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, malaise, tachycardia, urticaria, pancreatitis, cholelithiasis, cholecystitis, hypoglycaemia, anaphylactic reaction, dehydration, acute renal failure and renal impairment. **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. Full prescribing information is available upon request. **Edition 5.0.**

For Healthcare Professionals only.

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