Prescribing Information
Please refer to the Saxenda® summary of product characteristics for full information.

Saxenda®Liraglutide injection 3 mg.
Saxenda® 6 mg/mL solution for injection in a pre-filled pen. One pre-filled pen contains 18mg liraglutide in 3mL.

Indication: 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.
Posology and administration: Saxenda® is for once daily subcutaneous use only. Is administered once daily at any time, independent of meals. It is preferable that Saxenda® is injected around the same time of the day. Recommended starting dose is 0.6 mg once daily. Dose should be increased to 3.0 mg once daily in increments of 0.6 mg with at least one week intervals to improve gastro-intestinal (GI) tolerability. If escalation to the next dose step is not tolerated for two consecutive weeks, consider discontinuing treatment. 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. Daily doses higher than 3.0 mg are not recommended. No dose adjustment is required based on age but therapeutic experience in patients ≥75 years is limited and not recommended. No dose adjustment required for patients with mild or moderate renal impairment or mild or moderate hepatic impairment but it should be used with caution. Saxenda® is not recommended for use in patients with severe renal impairment including end-stage renal disease, or severe hepatic impairment or children and adolescents below 18 years.
Contraindications: Hypersensitivity to the active substance or to any of the excipients.
Special warnings and precautions for use: There is no clinical experience in patients with congestive heart failure New York Heart Association (NYHA) class IV and Saxenda® is not recommended for use in these patients. It is also not recommended in patients with eating disorders or treatment with medicinal products that may cause weight gain, as Saxenda® for weight management was not investigated in subjects with mild or moderate hepatic impairment; it should be used with caution in these patients. Use of Saxenda® is not recommended in patients with inflammatory bowel disease and diabetic gastroparesis since it is associated with transient GI adverse reactions including nausea, diarrhoea and vomiting. Acute pancreatitis has been observed with the use of GLP-1 receptor agonists, patients should be informed of the characteristic symptoms. If pancreatitis is suspected, Saxenda® should be discontinued. If acute pancreatitis is confirmed, Saxenda® should not be restarted. In weight management clinical trials, a higher rate of cholelithiasis and cholecystitis was observed in patients on Saxenda® than those on placebo, therefore patients should be informed of characteristic symptoms. Thyroid adverse events such as goitre have been reported in particular in patients with pre-existing thyroid disease. Saxenda® should be used with caution in patients with thyroid disease. An increased risk in heart rate was observed in clinical trials. For patients who experience a clinically relevant sustained increase in resting heart rate, treatment with Saxenda® should be discontinued. There is a risk of dehydration in relation to GI side effects associated with GLP-1 receptor agonists. Precautions should be taken to avoid fluid depletion. Patients with type 2 diabetes mellitus receiving Saxenda® in combination with insulin and/or sulfonylurea may have an increased risk of hypoglycaemia.
Fertility, pregnancy and lactation: Saxenda® should not be used during pregnancy. If a patient wishes to become pregnant, or pregnancy occurs, treatment with Saxenda® should be discontinued. It should not be used during breast-feeding.
Undesirable effects: Very common(≥1/10); nausea, vomiting, diarrhoea, constipation. **Common (≥1/100 to <1/10);** hypoglycaemia, insomnia, dizziness, dysgeusia, dry mouth, dyspepsia, gastritis, gastro-oesophageal reflux disease, abdominal pain upper, flatulence, eructation, abdominal distension, cholelithiasis, injection site reactions, asthenia, fatigue, increased lipase, increased amylase. **Uncommon (≥1/1,000 to <1/100);** dehydration, tachycardia, pancreatitis, cholecystitis, urticaria, malaise, delayed gastric emptying **Rare (≥1/10,000 to <1/1,000);** anaphylactic reaction, acute renal failure, renal impairment. The Summary of Product Characteristics should be consulted for a full list of side effects.
MA numbers and Basic NHS Price:
5 x 3 ml pre-filled pens EU/1/15/992/003, £196.20.
Legal category: POM.
Full 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.
Date last revised: December 2019

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.