

This meeting is organised and funded by Novo Nordisk A/S.

The information presented at this symposium is intended for healthcare professionals only.

Exploring different therapeutic approaches to chronic obesity management

Sunday 28 April 2019, 16.30–18.00
Armadillo, Scottish Event Campus,
Glasgow, UK

Symposium agenda

- 16.30–16.40 Welcome and introduction**
Chair: Richard Holt (UK)
 - 16.40–17.00 Exploring the potential of structured dietary programmes for the treatment of obesity (2-year data from the DiRECT trial)**
Michael Lean (UK)
 - 17.00–17.20 Intensive behavioural therapy in clinical weight management**
Thomas Wadden (US)
 - 17.20–17.40 Metabolic surgery from a non-specialist perspective**
Rachel Batterham (UK)
 - 17.40–17.55 Diets, surgery and pharmacotherapy: how can clinical guidelines best support treatment of patients?**
All faculty
 - 17.55–18.00 Summary and close**
Richard Holt
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This is a promotional symposium sponsored by Novo Nordisk, prescribing information will be made available during the meeting.

All speakers receive an honorarium for this meeting.

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. Saxenda® is administered once daily at any time, independent of meals. It should be injected in the abdomen, thigh or upper arm. It must not be administered intravenously or intramuscularly. The injection site and timing can be changed without dose adjustment. However, 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. Saxenda® should not be used in combination with another GLP-1 receptor agonist. When initiating treatment, consider reducing the dose of concomitantly administered insulin or insulin secretagogues (such as sulfonylureas) to reduce risk of hypoglycaemia. Blood glucose self-monitoring is necessary to adjust the dose of insulin or insulin-secretagogues. 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 (creatinine clearance ≥ 30 mL/min) 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 (creatinine clearance < 30 mL/min), 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: Saxenda® must not be used as a substitute for insulin in patients with diabetes mellitus nor should it be mixed with other injectables (e.g. insulins). Diabetic ketoacidosis has been reported 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 therefore Saxenda® is not recommended for use in these patients. Due to limited experience, Saxenda® is not recommended in patients: aged ≥ 75 years, 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. 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. Heart rate should be monitored at regular intervals and patients informed of the symptoms of increased heart rate. 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. Signs and symptoms of dehydration, including renal impairment and acute renal failure have been reported. Precautions should be taken to avoid fluid depletion. Patients with type 2 diabetes mellitus receiving Saxenda® in combination with a sulfonylurea may have an increased risk of hypoglycaemia. The addition of Saxenda® in patients treated with insulin has not been evaluated.

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 is not known whether Saxenda® is excreted in human milk. Because of lack of experience, it should not be used during breastfeeding. Apart from a slight decrease in the number of live implants, animal studies did not indicate harmful effects with respect to fertility.

Undesirable effects: Very common ($\geq 1/10$); nausea, vomiting, diarrhoea, constipation. Common ($\geq 1/100$ 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 ($\geq 1/1,000$ to $< 1/100$); dehydration, tachycardia, pancreatitis, cholecystitis, urticaria, malaise. Rare ($\geq 1/10,000$ 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.

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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.

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