Saxenda® guide for pharmacists

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Saxenda®
liraglutide injection

This quick guide was created to inform you about Saxenda®, and prepare you for any questions you might receive regarding dosing, administration, and handling of Saxenda®, and the Saxenda® pen. *Please note that you may only discuss this information with patients who have already received a Saxenda® prescription from their healthcare professional (HCP).*

This guide, which is not to be shared with patients, can be used as a supplement to the Saxenda® Patient Brochure, which may be handed out to patients if they have not received one from their HCP. Together, the information in these tools can help patients:

- Get started on Saxenda®
- Establish short-term and long-term goals
- Understand how to manage side effects
- Learn how to track their progress

1 What is Saxenda®?

The indication[1]

Saxenda® is the only glucagon-like peptide-1 (GLP-1) receptor agonist approved by SAHPRA, for weight management in adults.

- Prescribed as an adjunct to a reduced-calorie diet and increased physical activity 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 (pre-diabetes and type 2 diabetes mellitus), hypertension, dyslipidaemia, or obstructive sleep apnoea.

SAHPRA = South African Health Products Regulatory Authority

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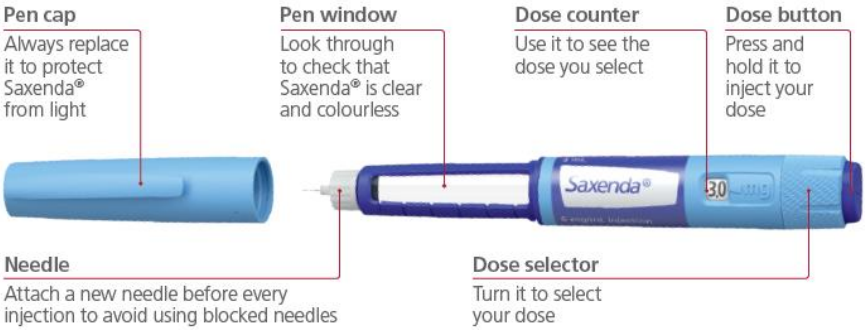
Note: *The information in this material is NOT intended as a substitute for the Professional Information and should not be shared with patients. Patients should be instructed to refer to the Professional Information for comprehensive information regarding what they should know when starting Saxenda® and should consult their doctor if they have any additional questions.*

2 Saxenda® pen

Features and functions

- Review features and functions of the prefilled Saxenda® pen with patients
- The pen is designed to be used with NovoFine® or NovoTwist® disposable needles up to a length of 8 mm and as thin as 32G[1]
- Needles are sold separately and may require a prescription



3 Administration

How to use the Saxenda® pen[1]

- Patients may need guidance on the steps required to administer Saxenda®
- Patients may need a reminder to inject Saxenda® once daily, regardless of when they eat meals
- Note that the timing of injection can be changed without a dose adjustment - but it's preferable that Saxenda® be injected around the same time each day

1. Check the Saxenda® pen

2. Attach a new needle

3. Check the Saxenda® flow

4. Select the dose

5. Inject the dose

6. Remove the needle

Note: *This is a quick guide. For more detailed instructions, refer to the Professional Information .*

Administration (cont'd)

Where to inject[1]

- Patients should inject Saxenda® subcutaneously into the waist (abdomen), front of the thighs, or upper arm
- Saxenda® should not be injected into a vein or a muscle
- If necessary, the injection site can be changed without changing the dose

4

Dosing

Information on dose escalation[1]

- Patients should follow a 4-week dose-escalation schedule to achieve the full 3 mg dose
- The Saxenda® starting dose is 0.6 mg per day for 1 week
- The dose should be increased to 3.0 mg daily in increments of 0.6 mg at intervals of at least 1 week to improve gastrointestinal (GI) tolerability
  - If escalation to the next dose step is not tolerated for 2 consecutive weeks, consider discontinuing treatment

In case of a missed dose

- If patients forget a dose, and it's within 12 hours of when they usually take it, they should inject it as soon as they remember[1]
- If there is less than 12 hours to the next dose, the patient should not take the missed dose and resume the once-daily regimen with the next scheduled dose[1]
- Patients should not take a double dose or increase the dose on the following day to make up for the missed dose[1]

5 Storing and handling

Proper handling of pens and needles[1]

- Following first use, Saxenda® pens should be discarded after 30 days, even if they still contain medication
- Do not freeze the Saxenda® pen. If frozen, do not use
- Each Saxenda® pen is for use by a single patient
- Never share a Saxenda® pen between patients, even if the needle is changed
- Injection needle should be discarded after each injection and pen stored without a needle attached

	How to Store	
	IN REFRIGERATOR *(2°C-8°C)*	***ROOM TEMPERATURE*** *(BELOW 30°C)*
New, unused Saxenda®	✓	**NOT PERMITTED**
After first use	✓	✓

6 Side effects

What patients may experience

The most common side effects seen in clinical studies with Saxenda® were GI events and headache.[1,2]

- Most episodes of GI events were mild to moderate and transient[1]
- The reactions usually occurred during the first weeks of treatment and most of them diminished within a few days or weeks on continued treatment[1]
- The majority did not lead to discontinuation of therapy[1]

Nausea was the most common side effect.[2]

- The dose-escalation schedule was specifically designed to minimise potential GI symptoms[1]

Note: *The information in this material is NOT intended as a substitute for the Patient Information Leaflet. Patients should be instructed to refer to the Professional information for comprehensive information regarding side effects, and to discuss them with their HCP. Please refer to the Saxenda® Professional Information for a complete overview of side effects.*

7 16-week weight-loss assessment

An important evaluation of efficacy

HCPs will evaluate patients' weight loss at 16 weeks (4 weeks on dose escalation and 12 weeks on full dose) to determine whether they should continue treatment with Saxenda®.

- According to the label, treatment with Saxenda® should be discontinued after 12 weeks on the 3 mg/day dose, if patients have not lost at least 5 % of their initial body weight[1]

The importance of keeping or scheduling this appointment with patients' HCPs should be emphasised.

References: 1. Saxenda® Professional Information, 12 September 2022. **2.** Pi-Sunyer X, Astrup A, Fujioka K, *et al*; for the SCALE Obesity and Prediabetes NN8022-1839 Study Group. A randomized, controlled trial of 3.0 mg of liraglutide in weight management. *N Engl J Med*. 2015;373(1):11-22 and supplementary appendix. doi:10.1056/NEJMoa1411892.

Abbreviated professional information

Scheduling Status: S4 **Name of the medicine:** Saxenda® **Qualitative and quantitative composition:** One ml of solution contains 6 mg of liraglutide and phenol 0,55 % m/v as the preservative. **Therapeutic indications:** Adults: Saxenda® is indicated as an adjunct to a reduced-calorie diet and increased physical activity for medically supervised chronic weight management programme 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 (pre-diabetes and type 2 diabetes mellitus), hypertension, dyslipidaemia, or obstructive sleep apnoea. Adolescents: Saxenda® can be used as an adjunct to a healthy nutrition and physical activity counselling for weight management in adolescent patients from the age of 12 years and above with: • body weight above 60 kg and • obesity (BMI corresponding to ≥30 kg/m² for adults by international cut-off points)*.

*IOTF BMI cut-off points for obesity by sex between 12–18 years

Age (years)		12	12.5	13	13.5	14	14.5	15	15.5	16	16.5	17	17.5	18
Body mass index 30 kg/m²	Males	26.02	26.43	26.84	27.25	27.63	27.98	28.30	28.60	28.88	29.14	29.41	29.70	30.00
	Females	26.67	27.24	27.76	28.20	28.57	28.87	29.11	29.29	29.43	29.56	29.69	29.84	30.00

Posology and method of administration: 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 intervals 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. Saxenda® is for subcutaneous use only. It must not be administered intravenously or intramuscularly. Saxenda® is administered once daily at any time, independent of meals. However, it is preferable that Saxenda® is injected around the same time of the day. It should be injected in the abdomen, thigh or upper arm. Patients must be instructed to perform continuous rotation of the injection site to reduce the risk of developing cutaneous amyloidosis. There may be a potential risk of change in Saxenda® absorption or effect following Saxenda® injections at sites with cutaneous amyloidosis. Saxenda® should not be used in combination with another GLP-1 receptor agonist. When initiating Saxenda®, consider reducing the dose of concomitantly administered insulin or insulin secretagogues (such as sulfonylureas) to reduce the risk of hypoglycaemia. Saxenda® is not recommended for use in children below 12 years of age or in adolescents with a body weight below or equal to 60 kg due to lack of data. **Contraindication:** • Hypersensitivity to liraglutide or to any of the excipients listed under Composition. • Pregnancy and lactation. **Special warnings and precautions for use:** Saxenda® must not be used as a substitute for insulin. There is no clinical experience in patients with congestive heart failure New York Heart Association (NYHA) class IV and Saxenda® is therefore not recommended for use in these patients. The safety and efficacy of Saxenda® have not been established in the following patients, viz: • 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, • With inflammatory bowel disease and diabetic gastroparesis. Use in these patients is not recommended. 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, Saxenda® should be discontinued; if acute pancreatitis is confirmed, Saxenda® should not be restarted. In the absence of other signs and symptoms of acute pancreatitis, elevations in pancreatic enzymes alone are not predictive of acute pancreatitis. In clinical trials, a higher rate of cholelithiasis and cholecystitis was observed in patients treated with Saxenda® 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 in patients with pre-existing thyroid disease. Saxenda® should therefore be used with caution in patients with thyroid disease. An increase in heart rate was observed 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 Saxenda® should be discontinued. Patients treated with Saxenda® should be advised of the potential risk of dehydration in relation to gastrointestinal side effects and take precautions to avoid fluid depletion. Patients with type 2 diabetes receiving Saxenda® in combination with insulin and/or sulphonylurea have an increased risk of hypoglycaemia. **Fertility, pregnancy and lactation:** Saxenda® should not be used during pregnancy and lactation. **Undesirable effects:** Gastrointestinal reactions were the most frequently reported adverse reactions during treatment with Saxenda®. Very common side effects are nausea, vomiting diarrhoea, constipation, headache. Common side effects include: Hypoglycaemia, insomnia, dizziness, dysgeusia, dry mouth, dyspepsia, gastritis, gastro-oesophageal reflux disease, abdominal pain upper, flatulence, eructation, abdominal distension, cholelithiasis, injection site reactions, cutaneous amyloidosis, asthenia & fatigue, increased lipase/increased amylase. Uncommon side effects include: dehydration, tachycardia, pancreatitis, cholecystitis, urticaria & malaise. Rare side effects include: anaphylactic reaction, acute renal failure & renal impairment. **Overdose:** With overdose, the patients reported severe nausea, vomiting and diarrhoea, but recovered without complications. Severe hypoglycaemia has also been observed. In the event of overdosage, 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. **Reg. No.:** 50/21.13/1091. For full prescribing information, refer to the Professional Information approved by the Regulatory Authority. *Ver. 12/09/2022.*

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Novo Nordisk (Pty) Ltd. Reg. No.: 1959/000833/07. 150 Rivonia Road, 10 Marion Street Office Park, Building C1, Sandton, Johannesburg, 2196, South Africa. Tel: (011) 202 0500. Fax: (011) 807 7989. www.novonordisk.com. 23969T. ZA24SX00011 March 2024.

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