

*I had the will to start a  
business from scratch.  
But I still need help to lose  
weight and keep it off.*

Your patients with obesity have the **will**.  
You can offer them the **way**.



SARAH, consultant;  
Age: 43 BMI: 37  
This is not a real patient  
but only an illustration.

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  $\geq 30$  kg/m<sup>2</sup> (obese), or  $\geq 27$  kg/m<sup>2</sup> to  $< 30$  kg/m<sup>2</sup> (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.

Prescribing information and adverse events reporting information can be found on page 15.



**Saxenda**®  
liraglutide injection 3 mg



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but only an illustration.

# Obesity is a chronic disease<sup>1</sup>



## **Obesity requires long-term management<sup>1-3</sup>**

Recognised by health organisations as a disease, including World Obesity Federation, The Obesity Society, and European Association for the Study of Obesity.



## **Obesity is associated with multiple complications<sup>4-6</sup>**

Cardiovascular (CV) disease is the leading cause of death in people with obesity.

40% of cancers diagnosed are associated with overweight and obesity.



## **There are physiological changes after weight loss that drive weight regain<sup>7-9</sup>**

Changes in appetite-regulating hormones after weight loss increase hunger and decrease satiety, and persist for at least 1 year.



## **Weight management brings health benefits<sup>10-14</sup>**

Weight loss of 5% or more reduces the risk of type 2 diabetes and improves sleep apnoea.

# Patients taking Saxenda® lost weight and kept it off in a 1-year trial versus placebo<sup>15</sup>

**9.2%\*** mean weight loss with Saxenda® completers<sup>15,16</sup>

**1<sup>out of</sup> 3** (33.1%) taking Saxenda® and 10.6% patients on placebo lost >10% ( $P < 0.001$  vs placebo)<sup>17</sup>

Patients taking Saxenda® (n=2437) had a baseline body weight of 106.3 kg. Completers' mean weight loss at week 56 was ~8.4 kg.<sup>15\*</sup>

Patients taking placebo (n=1225) had a baseline body weight of 106.3 kg. Mean weight loss at week 56 was 2.8 kg.<sup>15</sup>

\* $P < 0.001$  vs placebo.<sup>15,16</sup>



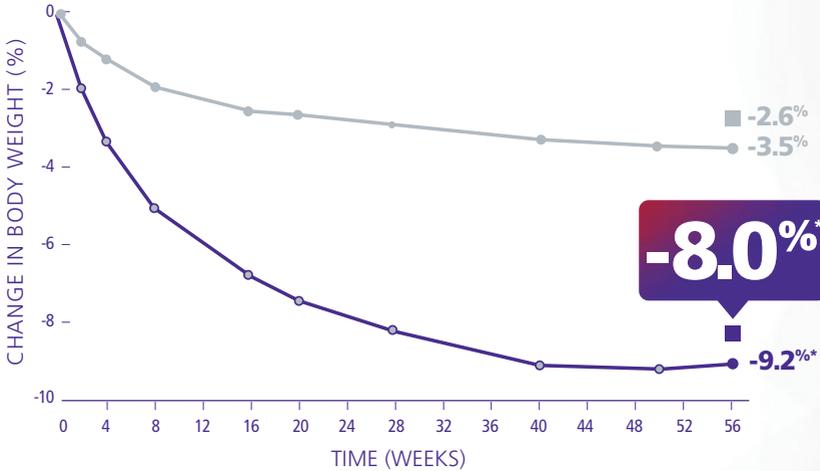
*“ It is really hard and frustrating to lose weight and keep it off. That’s why I am so excited about Saxenda®. ”*

**SARAH** Age: 43 BMI: 37  
**Complications:** Hypertension, osteoarthritis

This is not a real patient but only an illustration.

# More patients taking Saxenda<sup>®</sup> lost weight and kept it off in a 1-year trial<sup>15</sup>

## Change in body weight from baseline<sup>15-17</sup>



— Saxenda<sup>®</sup> + diet and exercise (n=2487)  
 ■ Week 56 LOCF  
 ● Week 56 Completer

— Placebo + diet and exercise (n=1244)  
 ■ Week 56 LOCF  
 ● Week 56 Completer

Data are observed means.  
 LOCF=last observation carried forward.  
 \* $P < 0.001$  vs placebo.<sup>15,16</sup>

72% of patients randomised to Saxenda<sup>®</sup> (1789 of 2487) completed the trial vs 64% treated with placebo (801 of 1244).<sup>17</sup>

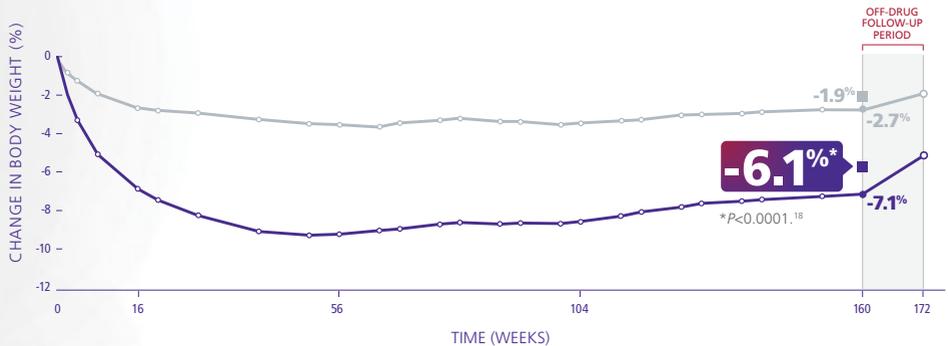


Patients treated with Saxenda<sup>®</sup> experienced an observed mean waist circumference **reduction of 8.2 cm** vs 3.9 cm with placebo ( $P < 0.001$ ).<sup>17</sup>

In the SCALE trials the three prespecified coprimary end points, assessed at week 56, were weight change from baseline, the proportion of patients who lost at least 5% of their baseline body weight, and the proportion of patients who lost more than 10% of their baseline body weight.<sup>16,17</sup>

# Patients treated with Saxenda® lost weight and sustained their weight loss for 3 years vs placebo<sup>15</sup>

## Change in body weight from baseline<sup>18</sup>



— Saxenda® + diet and exercise (n=1505)

— Placebo + diet and exercise (n=749)

■ Week 160 LOCF

■ Week 160 LOCF

● Week 160 Completer

● Week 160 Completer

Line graphs are observed means.  
LOCF=last observation carried forward.

*“ I am managing my weight.  
That’s what I think when I take Saxenda®. ”*



**LINDA** | Age: 40 | BMI: 36  
Complications: Hypertension, pre-diabetes

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but only an illustration.



PRE-DIABETES AND TYPE 2 DIABETES

# Saxenda<sup>®</sup> lowered blood glucose and reduced the risk of type 2 diabetes vs placebo<sup>15,18</sup>

## AFTER 3 YEARS



**~80%**

**Risk reduction for development of type 2 diabetes relative to placebo<sup>18</sup>**

**Absolute risk reduction of 0.04.**

**Hazard ratio of 0.2 (95% CI 0.13-0.34) for risk of developing type 2 diabetes vs placebo.<sup>18</sup>**

By week 160, 26 (2%) of 1472 individuals in the Saxenda<sup>®</sup> group versus 46 (6%) of the 738 in the placebo group were diagnosed with diabetes while on treatment.

Primary objective was to evaluate the proportion of individuals with T2D at 160 weeks and primary endpoint was time to onset of T2D. In patients treated with Saxenda<sup>®</sup>, time to onset of type 2 diabetes was 2.7 times longer vs placebo (95% CI, 1.9 to 3.9,  $P < 0.0001$ ).<sup>15,18</sup>

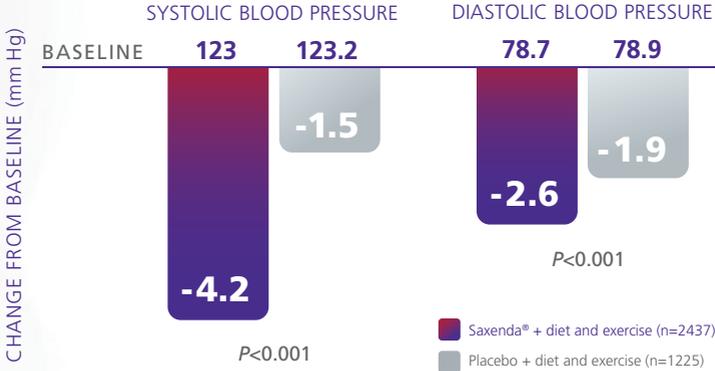
Hazard ratio derived from the primary Weibull analysis.<sup>18</sup>

**Saxenda<sup>®</sup> is not indicated for the treatment of type 2 diabetes.**



## BLOOD PRESSURE

# Saxenda® was observed to provide reductions in blood pressure vs placebo<sup>17</sup>



Results from a 56 week, double-blind trial involving 3731 patients who did not have type 2 diabetes and who had a BMI of at least 30 or a BMI of at least 27 if they had treated or untreated dyslipidemia or hypertension.<sup>17</sup>



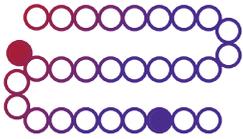
*“ It feels good to be doing something so positive. ”*

**ROBERTO** | Age: 48 | BMI: 39  
**Complications:** Hypertension, dyslipidaemia, sleep apnoea

This is not a real patient but only an illustration.

In the SCALE trials changes from baseline in cardiometabolic biomarkers was a secondary endpoint.<sup>17</sup>

# Similar to natural GLP-1, Saxenda® works in the brain\* to decrease appetite and thereby reduce food intake<sup>15</sup>

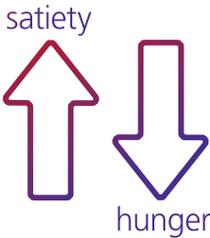


GLP-1 is a naturally occurring hormone that is released in response to food intake and acts as a physiological regulator of appetite<sup>15,19</sup>

Saxenda® is 97% similar to natural GLP-1<sup>15†</sup>



Saxenda® is believed to work in the hypothalamus where it interacts with specific neurons involved in the regulation of appetite and food intake<sup>20\*</sup>



Saxenda® increases feelings of satiety and decreases hunger<sup>15</sup>



As a result of its mechanism of action (MoA), patients taking Saxenda® feel satisfied and eat less food, leading to weight loss<sup>15</sup>

\*Shown in animal models.  
The exact MoA is unknown.

†Saxenda® is the result of 2 structural modifications to natural GLP-1 that prolong its half-life from less than 2 minutes to approximately 13 hours, when injected subcutaneously, allowing for once-daily dosing.<sup>21,22</sup>

# The long-term efficacy and safety profile of Saxenda® has been well documented



6 SCALE clinical trials included  
**6036 patients**<sup>15,23,24</sup>



**3-year data validated**  
 the long-term efficacy and safety  
 profile of Saxenda®<sup>18</sup>



The most common adverse events  
 were gastrointestinal (GI) disorders.<sup>15,23,24</sup>

**Most episodes were mild  
 to moderate and transient.**<sup>15,23,24</sup>

## Adverse events:

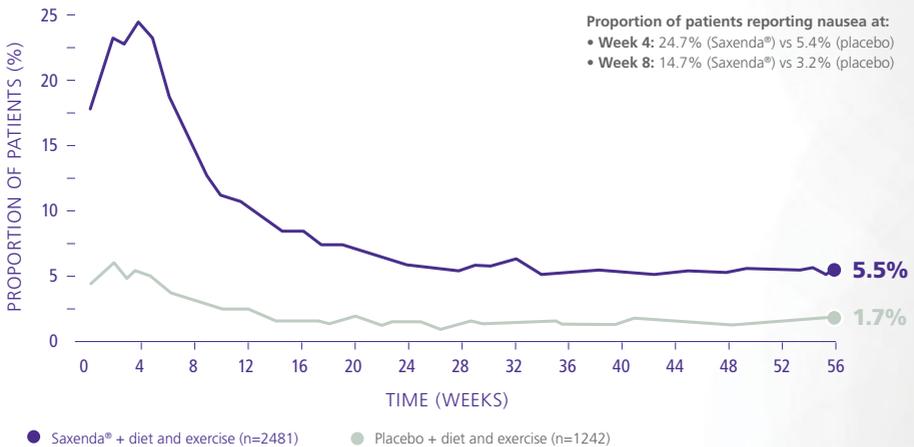
**Very common**(≥1/10); nausea, vomiting, diarrhoea, constipation. **Common** (≥1/100 to <1/10); hypoglycaemia, insomnia, dizziness, dysgeusia, dry mouth, dyspepsia, gastritis, gastro-oesophageal reflux disease, abdominal pain upper, flatulence, eructation, abdominal distension, cholelithiasis, injection site reactions, asthenia, fatigue, increased lipase, increased amylase.

Please refer to Saxenda® Summary of Product Characteristics for full safety and dosing information.

# Most common adverse events were GI disorders<sup>15,17</sup>

- The 4-week dose-escalation schedule was designed to minimise GI symptoms<sup>15</sup>
- Some patients withdrew due to adverse events (9.9% with Saxenda® vs 3.8% with placebo), but overall, more patients completed the trial with Saxenda® than with placebo (72% vs 64%, respectively)<sup>17</sup>

## ↓ Prevalence of nausea in a 56-week trial with 3731 patients<sup>16,17</sup>



## Support your patients in managing nausea with these suggestions<sup>25</sup>:



### TRY TO

- Eat smaller meals
- Stop eating when full
- Drink plenty of water
- Change the time of day Saxenda® is taken



### AVOID

- Eating fatty or fried foods
- Eating spicy foods with strong smells
- High-fibre food
- Smoking or drinking alcohol

Most GI disorders were mild to moderate and transient.<sup>15</sup>

Adjust the dose escalation schedule as necessary.<sup>25</sup>

Based on patient materials from the SCALE trials.<sup>25</sup>

# Dose escalation improves gastro-intestinal tolerability<sup>15</sup>

MAINTENANCE DOSE

WEEK 5

3.0 mg

WEEK 4

2.4 mg

WEEK 3

1.8 mg

WEEK 2

1.2 mg

WEEK 1

0.6 mg



# Show your patients how to inject

## Injection instructions

### 1 check pen



### 2 attach needle



### 3 check flow



### 4 select dose



### 5 inject dose



### 6 remove needle



Once-daily Saxenda® can be taken any time of day, independent of meals.<sup>15</sup>

The Saxenda® pen is designed to be used with needles up to a length of 8 mm and as thin as 32G, such as the NovoFine® or NovoTwist® needles.

Please see instructions for use for dosing and administration.

## References

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## Prescribing information

### 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  $\geq 30$  kg/m<sup>2</sup> (obesity) or  $\geq 27$  kg/m<sup>2</sup> to  $< 30$  kg/m<sup>2</sup> (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  $\geq 75$  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 ( $\geq 1/10$ );** 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, delayed gastric emptying **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 Bagsvaerd, Denmark. **Date last revised:** December 2019

**Adverse events should be reported.**  
**Reporting forms and information can be found at**  
**[www.mhra.gov.uk/yellowcard](http://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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UK19SX00106

# Saxenda® in summary



Patients achieved significant and sustained weight loss throughout 1-year and 3-year trials vs placebo<sup>15,18</sup>



Similar to natural GLP-1, Saxenda® works to decrease appetite and thereby reduce food intake<sup>15</sup>



The long-term tolerability profile of Saxenda® has been well documented<sup>15,18</sup>

**Obesity is a chronic disease,<sup>1</sup>**  
and patients may need your help.



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UK20SX00030 Date of preparation: March 2020



**Saxenda®**  
liraglutide injection 3 mg