Saxenda®
6 mg/ml
Solution for injection in pre-filled pen

Qualitative and quantitative composition
1 ml of solution contains 6 mg of liraglutide*. One pre-filled pen contains 18 mg liraglutide in 3 ml.
*human glucagon-like peptide-1 (GLP-1) analogue produced by recombinant DNA technology in *Saccharomyces cerevisiae.*
For the full list of excipients, see *List of excipients.*

Pharmaceutical form
Solution for injection.
Clear and colourless or almost colourless, isotonic solution; pH=8.15.

Therapeutic indications
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 (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 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.

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 intervals to improve gastro-intestinal tolerability (see table 1). 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.

Table 1 Dose escalation schedule

	Dose	**Weeks**
Dose escalation 4 weeks	0.6 mg	1
	1.2 mg	1
	1.8 mg	1
	2.4 mg	1
Maintenance dose	3.0 mg	

Patients with type 2 diabetes mellitus
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. Blood glucose self-monitoring is necessary to adjust the dose of insulin or insulin-secretagogues.

Special populations

Elderly (≥65 years old)

No dose adjustment is required based on age. Therapeutic experience in patients ≥75 years of age is limited and use in these patients is not recommended (see *Special warnings and precautions for use* and *Pharmacokinetic properties*).

Renal impairment

No dose adjustment is required for patients with mild or moderate renal impairment (creatinine clearance ≥30 ml/min). Saxenda® is not recommended for use in patients with severe renal impairment (creatinine clearance <30 ml/min) including patients with end-stage renal disease (see *Special warnings and precautions for use, Undesirable effects* and *Pharmacokinetic properties*).

Hepatic impairment

No dose adjustment is recommended for patients with mild or moderate hepatic impairment. Saxenda® is not recommended for use in patients with severe hepatic impairment and should be used cautiously in patients with mild or moderate hepatic impairment (see *Special warnings and precautions for use* and *Pharmacokinetic properties*).

Paediatric population

The safety and efficacy of Saxenda® in children and adolescents below 18 years of age have not yet been established. Currently available data are described in sections *Undesirable effects, Pharmacodynamic properties* and *Pharmacokinetic properties* but no recommendation on posology can be made.

Method of administration

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. It should be injected in the abdomen, thigh or upper arm. 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, when the most convenient time of the day has been chosen. Saxenda® should not be mixed with other injectables (e.g. insulins).

If a dose is missed within 12 hours from when it is usually taken, the patient should take the dose as soon as possible. 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. An extra dose or increase in dose should not be taken to make up for the missed dose. For further instructions on administration, see *Special precautions for disposal and other handling.*

Contraindications

Hypersensitivity to liraglutide or to any of the excipients listed in *List of excipients.*

Special warnings and precautions for use

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 (see *Posology and method of administration*).

There is no clinical experience in patients with congestive heart failure New York Heart Association (NYHA) class IV, and liraglutide is therefore not recommended for use in these patients.
The safety and efficacy of liraglutide for weight management have not been established 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.

Use in these patients is not recommended (see *Posology*).
As liraglutide for weight management was not investigated in subjects with mild or moderate hepatic impairment, it should be used with caution in these patients (see *Posology* and *Pharmacokinetic properties*).

There is limited experience in patients with inflammatory bowel disease and diabetic gastroparesis. Use of liraglutide is not recommended in these patients since it is associated with transient gastrointestinal adverse reactions, including nausea, vomiting and diarrhoea.

Pancreatitis
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, liraglutide should be discontinued; if acute pancreatitis is confirmed, liraglutide should not be restarted.

Cholelithiasis and cholecystitis
In clinical trials for weight management, a higher rate of cholelithiasis and cholecystitis was observed in patients treated with liraglutide than in patients on placebo. The fact that substantial weight loss can increase the risk of cholelithiasis and thereby cholecystitis only partially explained the higher rate with liraglutide. Cholelithiasis and cholecystitis may lead to hospitalisation and cholecystectomy. Patients should be informed of the characteristic symptoms of cholelithiasis and cholecystitis.

Thyroid disease
In clinical trials in type 2 diabetes, thyroid adverse events, such as goitre have been reported in particular in patients with pre-existing thyroid disease. Liraglutide should therefore be used with caution in patients with thyroid disease.

Heart rate
An increase in heart rate was observed with liraglutide in clinical trials (see *Pharmacodynamic properties*). 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.

Dehydration

Signs and symptoms of dehydration, including renal impairment and acute renal failure, have been reported in patients treated with GLP-1 receptor agonists. 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.

Hypoglycaemia in patients with type 2 diabetes mellitus

Patients with type 2 diabetes mellitus receiving liraglutide in combination with insulin and/or sulfonylurea may have an increased risk of hypoglycaemia. The risk of hypoglycaemia may be lowered by a reduction in the dose of insulin and/or sulfonylurea.

Interaction with other medicinal products and other forms of interaction

In vitro, liraglutide has shown very low potential to be involved in pharmacokinetic interactions with other active substances related to cytochrome P450 (CYP) and plasma protein binding.

The small delay of gastric emptying with liraglutide may influence absorption of concomitantly administered oral medicinal products. Interaction studies did not show any clinically relevant delay of absorption and therefore no dose adjustment is required.

Interaction studies have been performed with 1.8 mg liraglutide. The effect on rate of gastric emptying was equivalent between liraglutide 1.8 mg and 3.0 mg, (paracetamol $AUC_{0\text{-}300\ min}$).

Few patients treated with liraglutide reported at least one episode of severe diarrhoea. Diarrhoea may affect the absorption of concomitant oral medicinal products.

Warfarin and other coumarin derivatives

No interaction study has been performed. A clinically relevant interaction with active substances with poor solubility or narrow therapeutic index such as warfarin cannot be excluded. Upon initiation of liraglutide treatment in patients on warfarin or other coumarin derivatives more frequent monitoring of International Normalised Ratio (INR) is recommended.

Paracetamol (Acetaminophen)

Liraglutide did not change the overall exposure of paracetamol following a single dose of 1,000 mg. Paracetamol C_{max} was decreased by 31% and median t_{max} was delayed up to 15 min. No dose adjustment for concomitant use of paracetamol is required.

Atorvastatin

Liraglutide did not change the overall exposure of atorvastatin following single dose administration of atorvastatin 40 mg. Therefore, no dose adjustment of atorvastatin is required when given with liraglutide. Atorvastatin C_{max} was decreased by 38% and median t_{max} was delayed from 1 h to 3 h with liraglutide.

Griseofulvin

Liraglutide did not change the overall exposure of griseofulvin following administration of a single dose of griseofulvin 500 mg. Griseofulvin C_{max} increased by 37% while median t_{max} did not change. Dose adjustments of griseofulvin and other compounds with low solubility and high permeability are not required.

Digoxin
A single dose administration of digoxin 1 mg with liraglutide resulted in a reduction of digoxin AUC by 16%; C_{max} decreased by 31%. Digoxin median t_{max} was delayed from 1 h to 1.5 h. No dose adjustment of digoxin is required based on these results.

Lisinopril
A single dose administration of lisinopril 20 mg with liraglutide resulted in a reduction of lisinopril AUC by 15%; C_{max} decreased by 27%. Lisinopril median t_{max} was delayed from 6 h to 8 h with liraglutide. No dose adjustment of lisinopril is required based on these results.

Oral contraceptives
Liraglutide lowered ethinylestradiol and levonorgestrel C_{max} by 12% and 13%, respectively, following administration of a single dose of an oral contraceptive product. t_{max} was delayed by 1.5 h with liraglutide for both compounds. There was no clinically relevant effect on the overall exposure of either ethinylestradiol or levonorgestrel. The contraceptive effect is therefore anticipated to be unaffected when co-administered with liraglutide.

Fertility, pregnancy and lactation
Pregnancy
There are limited data from the use of liraglutide in pregnant women. Studies in animals have shown reproductive toxicity (see *Preclinical safety data*). The potential risk for humans is unknown.
Liraglutide should not be used during pregnancy. If a patient wishes to become pregnant, or pregnancy occurs, treatment with liraglutide should be discontinued.

Breast-feeding
It is not known whether liraglutide is excreted in human milk. Animal studies have shown that the transfer of liraglutide and metabolites of close structural relationship into milk is low. Non-clinical studies have shown a treatment related reduction of neonatal growth in suckling rat pups (see *Preclinical safety data*). Because of lack of experience, Saxenda® should not be used during breast-feeding.

Fertility
Apart from a slight decrease in the number of live implants, animal studies did not indicate harmful effects with respect to fertility (see *Preclinical safety data*).

Effects on ability to drive and use machines
Saxenda® has no or negligible influence on the ability to drive and use machines.

Undesirable effects
Summary of the safety profile:
Saxenda® was evaluated for safety in 5 double-blind, placebo controlled trials that enrolled 5,813 obese patients or overweight patients with at least one weight-related comorbidity. Overall, gastrointestinal reactions were the most frequently reported adverse reactions during treatment with Saxenda® (see *Description of selected adverse reactions*).

Tabulated list of adverse reactions

Table 2 lists adverse reactions reported in long term phase 2 and phase 3 controlled trials. Adverse reactions are listed by system organ class and frequency. Frequency categories are defined as: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Table 2 Adverse reactions reported in phase 2 and phase 3 controlled trials

MedDRA system organ classes	**Very common**	**Common**	**Uncommon**	**Rare**
Immune system disorders				Anaphylactic reaction
Metabolism and nutrition disorders		Hypoglycaemia*	Dehydration	
Psychiatric disorders		Insomnia**		
Nervous system disorders		Dizziness Dysgeusia		
Cardiac disorders			Tachycardia	
Gastrointestinal disorders	Nausea Vomiting Diarrhoea Constipation	Dry mouth Dyspepsia Gastritis Gastro-oesophageal reflux disease Abdominal pain upper Flatulence Eructation Abdominal distension	Pancreatitis*** Delayed gastric emptying****	
Hepatobiliary disorders		Cholelithiasis***	Cholecystitis***	
Skin and subcutaneous tissue disorders			Urticaria	
Renal and urinary disorders				Acute renal failure Renal impairment
General disorders and administration site conditions		Injection site reactions Asthenia Fatigue	Malaise	
Investigations		Increased lipase Increased amylase		

*Hypoglycaemia (based on self-reported symptoms by patients and not confirmed by blood glucose measurements) reported in patients without type 2 diabetes mellitus treated with Saxenda® in combination with diet and exercise. Please see *Description of selected adverse reactions* for further information.
**Insomnia was mainly seen during the first 3 months of treatment.
***See *Special warnings and precautions for use.*
****From controlled phase 2, 3a and 3b clinical trials.

Description of selected adverse reactions:
Hypoglycaemia in patients without type 2 diabetes mellitus
In clinical trials in overweight or obese patients without type 2 diabetes mellitus treated with Saxenda® in combination with diet and exercise, no severe hypoglycaemic events (requiring third party assistance) were reported. Symptoms of hypoglycaemic events were reported by 1.6% of patients treated with Saxenda® and 1.1% of patients treated with placebo; however, these events were not confirmed by blood glucose measurements. The majority of events were mild.

Hypoglycaemia in patients with type 2 diabetes mellitus
In a clinical trial in overweight or obese patients with type 2 diabetes mellitus treated with Saxenda® in combination with diet and exercise, severe hypoglycaemia (requiring third party assistance) was reported by 0.7% of patients treated with Saxenda® and only in patients concomitantly treated with sulfonylurea. Also, in these patients documented symptomatic hypoglycaemia was reported by 43.6% of patients treated with Saxenda® and in 27.3% of patients treated with placebo. Among patients not concomitantly treated with sulfonylurea, 15.7% of patients treated with Saxenda® and 7.6% of patients treated with placebo reported documented symptomatic hypoglycaemic events (defined as plasma glucose ≤3.9 mmol/l accompanied by symptoms).

Hypoglycaemia in patients with type 2 diabetes mellitus treated with insulin
In a clinical trial in overweight or obese patients with type 2 diabetes mellitus treated with insulin and liraglutide 3.0 mg/day in combination with diet and exercise and up to 2 OADs, severe hypoglycaemia (requiring third party assistance) was reported by 1.5% of patients treated with liraglutide 3.0 mg/day. In this trial, documented symptomatic hypoglycaemia (defined as plasma glucose ≤3.9 mmol/l accompanied by symptoms) was reported by 47.2% of patients treated with liraglutide 3.0 mg/day and by 51.8% of patients treated with placebo. Among patients concomitantly treated with sulfonylurea, 60.9% of patients treated with liraglutide 3.0 mg/day and 60.0% of patients treated with placebo reported documented symptomatic hypoglycaemic events.

Gastrointestinal adverse reactions
Most episodes of gastrointestinal events were mild to moderate, transient and the majority did not lead to discontinuation of therapy. The reactions usually occurred during the first weeks of treatment and diminished within a few days or weeks on continued treatment.
Patients ≥65 years of age may experience more gastrointestinal effects when treated with Saxenda®.
Patients with mild or moderate renal impairment (creatinine clearance ≥30 ml/min) may experience more gastrointestinal effects when treated with Saxenda®.

Acute renal failure
In patients treated with GLP-1 receptor agonists, there have been reports of acute renal failure. A majority of the reported events occurred in patients who had experienced nausea, vomiting, or diarrhoea leading to volume depletion (see *Special warnings and precautions for use*).

Allergic reactions
Few cases of anaphylactic reactions with symptoms such as hypotension, palpitations, dyspnoea and oedema have been reported with marketed use of liraglutide. Anaphylactic reactions may potentially be life threatening. If an anaphylactic reaction is suspected, liraglutide should be discontinued and treatment should not be restarted (see *Contraindications*).

Injection site reactions
Injection site reactions have been reported in patients treated with Saxenda®. These reactions were usually mild and transitory and the majority disappeared during continued treatment.

Tachycardia
In clinical trials, tachycardia was reported in 0.6% of patients treated with Saxenda® and in 0.1% of patients treated with placebo. The majority of events were mild or moderate. Events were isolated and the majority resolved during continued treatment with Saxenda®.

Paediatric population
Saxenda® is not recommended for use in paediatric patients. Gastrointestinal disorders were the most frequently reported adverse events in two dose escalation studies completed so far.

Overdose
From clinical trials and post-marketing use of liraglutide overdoses have been reported up to 72 mg (24 times the recommended dose for weight management). Events reported included severe nausea and severe vomiting which are also the expected symptoms of an overdose with liraglutide. None of the reports included severe hypoglycaemia. All patients recovered without complications.
In the event of overdose, 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.

Pharmacodynamic properties
Pharmacotherapeutic group: Drugs used in diabetes, glucagon-like peptide-1 (GLP-1) analogues. ATC code: A10BJ02

Mechanism of action
Liraglutide is an acylated human glucagon-like peptide-1 (GLP-1) analogue with 97% amino acid sequence homology to endogenous human GLP-1. Liraglutide binds to and activates the GLP-1 receptor (GLP-1R).
GLP-1 is a physiological regulator of appetite and food intake, but the exact mechanism of action is not entirely clear. In animal studies, peripheral administration of liraglutide led to

uptake in specific brain regions involved in regulation of appetite, where liraglutide, via specific activation of the GLP-1R, increased key satiety and decreased key hunger signals, thereby leading to lower body weight.
GLP-1 receptors are also expressed in specific locations in the heart, vasculature, immune system, and kidneys. In mouse models of atherosclerosis, liraglutide prevented aortic plaque progression and reduced inflammation in the plaque. In addition, liraglutide had a beneficial effect on plasma lipids. Liraglutide did not reduce the plaque size of already established plaques.

Pharmacodynamic effects
Liraglutide lowers body weight in humans mainly through loss of fat mass with relative reductions in visceral fat being greater than for subcutaneous fat loss. Liraglutide regulates appetite by increasing feelings of fullness and satiety, while lowering feelings of hunger and prospective food consumption, thereby leading to reduced food intake. Liraglutide does not increase energy expenditure compared to placebo.
Liraglutide stimulates insulin secretion and lowers glucagon secretion in a glucose-dependent manner which results in a lowering of fasting and post-prandial glucose. The glucose-lowering effect is more pronounced in patients with pre-diabetes and diabetes compared to patients with normoglycaemia. Clinical trials suggest that liraglutide improves and sustains beta-cell function, according to HOMA-B, and the proinsulin-to-insulin ratio.

Clinical efficacy and safety
The efficacy and safety of liraglutide for weight management in conjunction with reduced caloric intake and increased physical activity were studied in four phase 3 randomised, double-blind, placebo-controlled trials which included a total of 5,358 patients.

Trial 1 (SCALE Obesity & Pre-Diabetes - 1839): A total of 3,731 patients with obesity (BMI ≥30 kg/m²), or with overweight (BMI ≥27 kg/m²) with dyslipidaemia and/or hypertension were stratified according to pre-diabetes status at screening and BMI at baseline (≥30 kg/m² or <30 kg/m²). All 3,731 patients were randomised to 56 weeks of treatment and the 2,254 patients with pre-diabetes at screening were randomised to 160 weeks of treatment. Both treatment periods were followed by a 12-week off drug/placebo observational follow-up period. Lifestyle intervention in the form of an energy-restricted diet and exercise counselling was background therapy for all patients.
The 56 week part of trial 1 assessed body weight loss in all the 3,731 randomised patients (2,590 completers).
The 160 week part of trial 1 assessed time to onset of type 2 diabetes in the 2,254 randomised patients with pre-diabetes (1,128 completers).
Trial 2 (SCALE Diabetes - 1922): A 56-week trial assessing body weight loss in 846 randomised (628 completers) obese and overweight patients with insufficiently controlled type 2 diabetes mellitus (HbA_{1c} range 7–10%). The background treatment at trial start was either diet and exercise alone, metformin, a sulfonylurea, a glitazone as single agents or any combination hereof.
Trial 3 (SCALE Sleep Apnoea - 3970): A 32-week trial assessing sleep apnoea severity and body weight loss in 359 randomised (276 completers) obese patients with moderate or severe obstructive sleep apnoea.
Trial 4 (SCALE Maintenance - 1923): A 56-week trial assessing body weight maintenance and weight loss in 422 randomised (305 completers) obese and overweight patients with

hypertension or dyslipidaemia after a preceding weight loss of ≥5% induced by a low-calorie diet.

Body weight
Superior weight loss was achieved with liraglutide compared to placebo in obese/overweight patients in all groups studied. Across the trial populations, greater proportions of the patients achieved ≥5% and >10% weight loss with liraglutide than with placebo. In the 160 weeks part of trial 1, the weight loss occurred mainly in the first year, and was sustained throughout 160 weeks.

- In trial 1, mean change from baseline in body weight at week 56 was -8.0% (-8.4 kg) for liraglutide vs -2.6% (-2.8 kg) for placebo (estimated treatment difference (ETD) (mean change in %): -5.4[95%CI -5.8; -5.0], p<0.0001, ETD (mean change in kg): -5.6[95%CI -6.0; -5.1], p<0.0001). The proportion of patients losing 5% and 10% weight loss at week 56 was 63.5% and 32.8% respectively for liraglutide vs 26.6% and 10.1% respectively for placebo (estimated odds ratio (of losing ≥5% body weight): 4.8[95%CI 4.1; 5.6], p<0.0001, estimated odds ratio (of losing >10% body weight): 4.3[95%CI 3.5; 5.3], p<0.0001).
- In trial 1, mean change from baseline in body weight at week 160 was -6.2% (-6.5 kg) for liraglutide vs -1.8% (-2.0 kg) for placebo (estimated treatment difference (ETD) (mean change in %): -4.3[95%CI -4.9; -3.7], p<0.0001, ETD (mean change in kg): -4.6[95%CI -5.3; -3.9], p<0.0001). The proportion of patients losing 5% and 10% weight loss at week 160 was 49.6% and 24.4% respectively for liraglutide vs 23.4% and 9.5% respectively for placebo (estimated odds ratio (of losing ≥5% body weight): 3.2[95%CI 2.6; 3.9], p<0.0001, estimated odds ratio (of losing >10% body weight): 3.1[95%CI 2.3; 4.1], p<0.0001).
- In trial 2, mean change from baseline in body weight at week 56 was -5.9% (-6.2 kg) for liraglutide vs -2.0% (-2.2 kg) for placebo (estimated treatment difference (ETD) (mean change in %): -4.0[95%CI -4.8; -3.1], p<0.0001, ETD (mean change in kg): -4.1[95%CI -5.0; -3.1], p<0.0001). The proportion of patients losing 5% and 10% weight loss at week 56 was 49.8% and 22.9% respectively for liraglutide vs 13.5% and 4.2% respectively for placebo (estimated odds ratio (of losing ≥5% body weight): 6.4[95%CI 4.1; 10.0], p<0.0001, estimated odds ratio (of losing >10% body weight): 6.8[95%CI 3.4; 13.8], p<0.0001).
- In trial 3, mean change from baseline in body weight at week 32 was -5.7% (-6.8 kg) for liraglutide vs -1.6% (-1.8 kg) for placebo (estimated treatment difference (ETD) (mean change in %): -4.2[95%CI -5.2; -3.1], p<0.0001, ETD (mean change in kg): -4.9[95%CI -6.2; -3.7], p<0.0001). The proportion of patients losing 5% weight loss at week 32 was 46.4% for liraglutide vs 18.1% for placebo (estimated odds ratio: 3.9[95%CI 2.4; 6.4], p<0.0001).
- In trial 4, more patients maintained the weight loss achieved prior to treatment initiation with liraglutide than with placebo (81.4% and 48.9%, respectively). Mean change from baseline in body weight at week 56 was -6.3% (-6.0 kg) for liraglutide vs -0.2% (-0.2 kg) for placebo (estimated treatment difference (ETD) (mean change in %): -6.1[95%CI -7.5; -4.6], p<0.0001, ETD (mean change in kg): -5.9[95%CI -7.3; -4.4], p<0.0001). The proportion of patients losing 5% and 10% weight loss at week 56 was 50.7% and 27.4% respectively for liraglutide vs 21.3% and 6.8% respectively for placebo (estimated odds ratio (of losing ≥5% body weight): 3.8[95%CI 2.4; 6.0],

p<0.0001, estimated odds ratio (of losing >10% body weight): 5.1[95%CI 2.7; 9.7], p<0.0001).

Data on weight loss, time course and cumulative distribution of weight change (%) are presented in figures 1, 2, and 3.

Weight loss response after 12 weeks with liraglutide (3.0 mg) treatment

Early responders were defined as patients who achieved ≥5% weight loss after 12 weeks on treatment dose of liraglutide (4 weeks of dose escalation and 12 weeks on treatment dose). In the 56 week part of trial 1, 67.5% achieved ≥5% weight loss after 12 weeks. In trial 2, 50.4% achieved ≥5% weight loss after 12 weeks. With continued treatment with liraglutide, 86.2% of these early responders are predicted to achieve a weight loss of ≥5% and 51% are predicted to achieve a weight loss of ≥10% after 1 year of treatment. The predicted mean weight loss in early responders who complete 1 year of treatment is 11.2% of their baseline body weight (9.7% for males and 11.6% for females). For patients who have achieved a weight loss of <5% after 12 weeks on treatment dose of liraglutide, the proportion of patients not reaching a weight loss of ≥10% after 1 year is 93.4%.

Glycaemic control

Treatment with liraglutide significantly improved glycaemic parameters across sub-populations with normoglycaemia, pre-diabetes and type 2 diabetes mellitus. In the 56 week part of trial 1, fewer patients treated with liraglutide had developed type 2 diabetes mellitus compared to patients treated with placebo (0.2% vs 1.1%). More patients with pre-diabetes at baseline had reversed their pre-diabetes compared to patients treated with placebo (69.2% vs 32.7%). From a baseline HbA_{1c} of 5.6%, patients in the liraglutide group had a mean HbA_{1c} reduction of -0.3% at week 56 vs -0.1% in the placebo group (ETD: -0.23[95%CI -0.25; -0.21], p<0.0001). From a baseline FPG of 5.3 mmol/l, patients in the liraglutide group had a mean FPG reduction of -0.4 mmol/l at week 56 vs -0.01 mmol/l in the placebo group (ETD: -0.38[95%CI -0.42; -0.35], p<0.0001). In the 160 week part of trial 1, the primary efficacy endpoint was the proportion of patients with onset of type 2 diabetes mellitus evaluated as time to onset. At week 160, while on treatment, 3% treated with Saxenda® and 11% treated with placebo were diagnosed with type 2 diabetes mellitus. The estimated time to onset of type 2 diabetes mellitus for patients treated with liraglutide 3.0 mg was 2.7 times longer (with a 95% confidence interval of [1.9, 3.9]), and the hazard ratio for risk of developing type 2 diabetes mellitus was 0.2 for liraglutide versus placebo. From a baseline HbA_{1c} of 5.8% in the liraglutide group and 5.7% in the placebo group, patients had a mean HbA_{1c} reduction of -0.4% and -0.1% at week 160, respectively (ETD: -0.21[95%CI -0.24; -0.18], p<0.0001). From a baseline FPG of 5.5 mmol/l, patients in the liraglutide group had a mean FPG reduction of -0.4 mmol/l at week 160 vs -0.04 mmol/l in the placebo group (ETD: -0.4[95%CI -0.5; -0.4], p<0.0001). In trial 2, from a baseline HbA_{1c} of 7.9%, patients in the liraglutide group had a mean HbA_{1c} reduction of -1.3% at week 56 vs -0.4% in the placebo group (ETD: -0.9[95%CI -1.1; -0.8], p<0.0001). From a baseline FPG of 8.8 mmol/l in the liraglutide group and 8.6 mmol/l in the placebo group, patients had a mean FPG reduction of -1.9 mmol/l and -0.1 mmol/l at week 56, respectively (ETD: -1.8[95%CI -2.1; -1.4], p<0.0001).

Cardiometabolic risk factors

Treatment with liraglutide significantly improved systolic blood pressure (SBP) and waist circumference compared with placebo. In trial 1, from a baseline SBP of 123.0 mmHg in the

liraglutide group and 123.3 mmHg in the placebo group, patients had a mean SBP reduction of -4.3 mmHg and -1.5 mmHg at week 56, respectively (ETD: -2.8[95%CI -3.6; -2.1], p<0.0001). From a baseline diastolic blood pressure (DBP) of 78.7 mmHg in the liraglutide group and 78.9 mmHg in the placebo group, patients had a mean DBP reduction of -2.7 mmHg and -1.8 mmHg at week 56, respectively (ETD: -0.9[95%CI -1.4; -0.4], p<0.05). From a baseline waist circumference of 115.0 cm in the liraglutide group and 114.5 cm in the placebo group, patients had a mean reduction of -8.2 cm and -4.0 cm at week 56, respectively (ETD: -4.2[95%CI -4.7; -3.7], p<0.0001). In trial 1, from a baseline SBP of 124.8 mmHg in the liraglutide group and 125.0 mmHg in the placebo group, patients had a mean SBP reduction of -3.2 mmHg and -0.4 mmHg at week 160, respectively (ETD: -2.8[95%CI -3.8; -1.8], p<0.0001). From a baseline diastolic blood pressure (DBP) of 79.4 mmHg in the liraglutide group and 79.8 mmHg in the placebo group, patients had a mean DBP reduction of -2.4 mmHg and -1.7 mmHg at week 160, respectively (ETD: -0.6[95%CI -1.3; 0.1]). From a baseline waist circumference of 116.6 cm in the liraglutide group and 116.7 cm in the placebo group, patients had a mean reduction of -6.9 cm and -3.4 cm at week 160, respectively (ETD: -3.5[95%CI -4.2; -2.8], p<0.0001). In trial 2, from a baseline SBP of 128.9 mmHg in the liraglutide group and 129.2 mmHg in the placebo group, patients had a mean SBP reduction of -3.0 mmHg and -0.4 mmHg at week 56, respectively (ETD: -2.6[95%CI -4.6; -0.6], p<0.0001). From a baseline diastolic blood pressure (DBP) of 79 mmHg in the liraglutide group and 79.3 mmHg in the placebo group, patients had a mean DBP reduction of -1.0 mmHg and -0.6 mmHg at week 56, respectively (ETD: -0.4[95%CI -1.7; 1.0], p=0.5918). From a baseline waist circumference of 118.1 cm in the liraglutide group and 117.3 cm in the placebo group, patients had a mean reduction of -6.0 cm and -2.8 cm at week 56, respectively (ETD: -3.2[95%CI -4.2; -2.2], p<0.0001).

Apnoea-Hypopnoea Index (AHI)

Treatment with liraglutide significantly reduced the severity of obstructive sleep apnoea as assessed by change from baseline in the AHI compared with placebo (-12.2 events/hour for liraglutide vs -6.1 events/hour for placebo, ETD: -6.1[95%CI -11.0; -1.2], p<0.05).

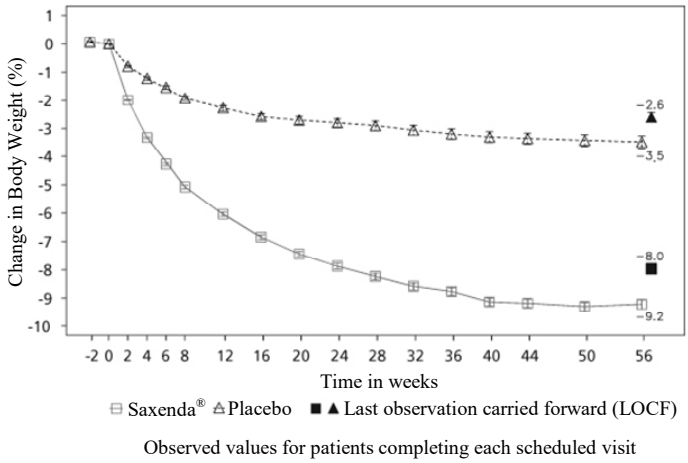


Figure 1 Change from baseline in body weight (%) by time in trial 1 (0–56 weeks)

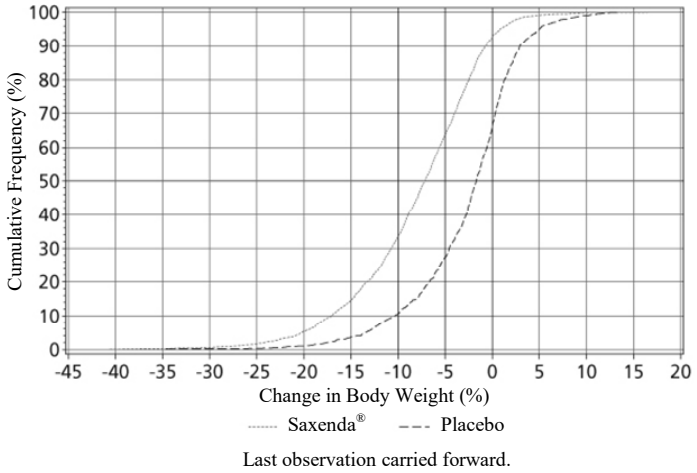


Figure 2 Cumulative distribution of weight change (%) after 56 weeks of treatment in trial 1

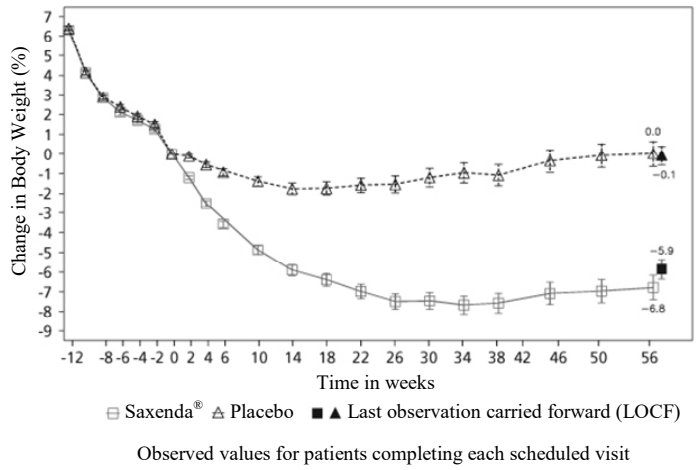


Figure 3 Change from randomisation (week 0) in body weight (%) by time in trial 4

Before week 0 patients were only treated with low-calorie diet and exercise. At week 0 patients were randomised to receive either Saxenda® or placebo.

Immunogenicity
Consistent with the potentially immunogenic properties of protein and peptide pharmaceuticals, patients may develop anti-liraglutide antibodies following treatment with liraglutide. In clinical trials, 2.5% of patients treated with liraglutide developed anti-liraglutide antibodies. Antibody formation has not been associated with reduced efficacy of liraglutide.

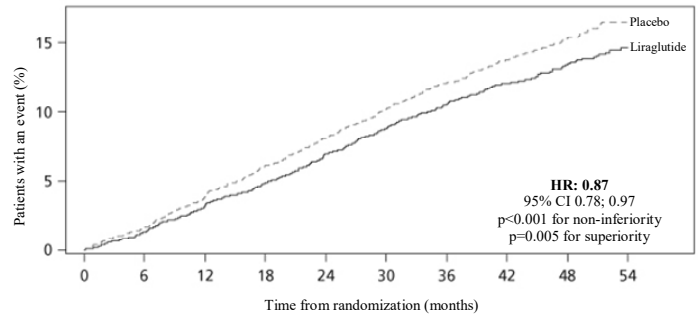
Cardiovascular evaluation
Major adverse cardiovascular events (MACE) were adjudicated by an external independent group of experts and defined as non-fatal myocardial infarction, non-fatal stroke and cardiovascular death. In all the long-term clinical trials with Saxenda®, there were 6 MACE for patients treated with liraglutide and 10 MACE for placebo treated patients. The hazard ratio and 95% CI is 0.33 [0.12; 0.90] for liraglutide versus placebo. A mean increase in heart

rate from baseline of 2.5 beats per minute (ranging across trials from 1.6 to 3.6 beats per minute) has been observed with liraglutide in clinical phase 3 trials. The heart rate peaked after approximately 6 weeks. The long-term clinical impact of this mean increase in heart rate has not been established. The change in heart rate was reversible upon discontinuation of liraglutide (see *Special warnings and precautions for use*).

The Liraglutide Effect and Action in Diabetes Evaluation of Cardiovascular Outcomes Results (LEADER®) trial included 9,340 patients with insufficiently controlled type 2 diabetes. The vast majority of these had established cardiovascular disease. Patients were randomly allocated to either liraglutide on a daily dose of up to 1.8 mg (4,668) or placebo (4,672), both on a background of standard of care.

The duration of exposure was between 3.5 and 5 years. The mean age was 64 years and the mean BMI was 32.5 kg/m². Mean baseline HbA_{1c} was 8.7 and had improved after 3 years by 1.2% in patients assigned to liraglutide and by 0.8% in patients assigned to placebo. The primary endpoint was the time from randomisation to first occurrence of any major adverse cardiovascular events (MACE): cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke.

Liraglutide significantly reduced the rate of major adverse cardiovascular events (primary endpoint events, MACE) vs placebo (3.41 vs 3.90 per 100 patient years of observation in the liraglutide and placebo groups, respectively) with a risk reduction of 13%, HR 0.87, [0.78, 0.97] [95% CI]) (p=0.005) (see figure 4).



Patients at risk

Placebo	4672	4587	4473	4352	4237	4123	4010	3914	1543	407
Liraglutide	4668	4593	4496	4400	4280	4172	4072	3982	1562	424

FAS: full analysis set.

Figure 4 Kaplan Meier plot of time to first MACE – FAS population

Paediatric population

Studies in the paediatric population are ongoing. Currently available results are too limited to draw conclusions on the efficacy of Saxenda® in children.

Pharmacokinetic properties

Absorption

The absorption of liraglutide following subcutaneous administration was slow, reaching maximum concentration approximately 11 hours post dosing. The average liraglutide steady

state concentration ($AUC_{\tau/24}$) reached approximately 31 nmol/l in obese (BMI 30–40 kg/m^2) patients following administration of 3.0 mg liraglutide. Liraglutide exposure increased proportionally with dose. Absolute bioavailability of liraglutide following subcutaneous administration is approximately 55%.

Distribution
The mean apparent volume of distribution after subcutaneous administration is 20–25 l (for a person weighing approximately 100 kg). Liraglutide is extensively bound to plasma protein (>98%).

Biotransformation
During 24 hours following administration of a single [^{3}H]-liraglutide dose to healthy subjects, the major component in plasma was intact liraglutide. Two minor plasma metabolites were detected (≤9% and ≤5% of total plasma radioactivity exposure).

Elimination
Liraglutide is endogenously metabolised in a similar manner to large proteins without a specific organ as major route of elimination. Following a [^{3}H]-liraglutide dose, intact liraglutide was not detected in urine or faeces. Only a minor part of the administered radioactivity was excreted as liraglutide-related metabolites in urine or faeces (6% and 5%, respectively). The urine and faeces radioactivity was mainly excreted during the first 6–8 days, and corresponded to three minor metabolites, respectively.
The mean clearance following subcutaneous administration of liraglutide is approximately 0.9–1.4 l/h with an elimination half-life of approximately 13 hours.

Special populations
Elderly: Age had no clinically relevant effect on the pharmacokinetics of liraglutide based on the results from a population pharmacokinetic analysis of data from overweight and obese patients (18 to 82 years). No dosage adjustment is required based on age.

Gender: Based on the results of population pharmacokinetic analysis, females have 24% lower weight adjusted clearance of liraglutide compared to males. Based on the exposure response data, no dose adjustment is necessary based on gender.

Ethnic origin: Ethnic origin had no clinically relevant effect on the pharmacokinetics of liraglutide based on the results of population pharmacokinetic analysis which included overweight and obese patients of White, Black, Asian and Hispanic/non-Hispanic groups.

Body weight: The exposure of liraglutide decreases with an increase in baseline body weight. The 3.0 mg daily dose of liraglutide provided adequate systemic exposures over the body weight range of 60–234 kg evaluated for exposure response in the clinical trials. Liraglutide exposure was not studied in patients with body weight >234 kg.

Hepatic impairment: The pharmacokinetics of liraglutide was evaluated in patients with varying degree of hepatic impairment in a single-dose trial (0.75 mg). Liraglutide exposure was decreased by 13–23% in patients with mild to moderate hepatic impairment compared to healthy subjects. Exposure was significantly lower (44%) in patients with severe hepatic impairment (Child Pugh score >9).

Renal impairment: Liraglutide exposure was reduced in patients with renal impairment compared to individuals with normal renal function in a single-dose trial (0.75 mg). Liraglutide exposure was lowered by 33%, 14%, 27% and 26%, respectively, in patients with mild (creatinine clearance, CrCl 50–80 ml/min), moderate (CrCl 30–50 ml/min), and severe (CrCl <30 ml/min) renal impairment and in end-stage renal disease requiring dialysis.

Paediatric population: Pharmacokinetic properties were assessed in clinical pharmacology studies in the paediatric population with obesity aged 12-17 years (14 patients, body weight 80-122 kg) and 7-11 years (16 patients, body weight 45-87 kg) respectively.

The liraglutide exposure in adolescents (age 12-17 years), was similar to that in adults with obesity. Exposure associated with 3.0 mg liraglutide was found to be comparable between the children aged 7 to 11, adolescents and adult subjects, after correction for body weight.

Preclinical safety data
Non-clinical data reveal no special hazards for humans based on conventional studies of safety pharmacology, repeat-dose toxicity, or genotoxicity.
Non-lethal thyroid C-cell tumours were seen in two year carcinogenicity studies in rats and mice. In rats, a no observed adverse effect level (NOAEL) was not observed. These tumours were not seen in monkeys treated for 20 months. These findings in rodents are caused by a non-genotoxic, specific GLP-1 receptor-mediated mechanism to which rodents are particularly sensitive. The relevance for humans is likely to be low but cannot be completely excluded. No other treatment related tumours have been found.
Animal studies did not indicate direct harmful effects with respect to fertility but slightly increased early embryonic deaths at the highest dose. Dosing with liraglutide during mid-gestation caused a reduction in maternal weight and foetal growth with equivocal effects on ribs in rats and skeletal variation in the rabbit. Neonatal growth was reduced in rats while exposed to liraglutide, and persisted in the post-weaning period in the high dose group. It is unknown whether the reduced pup growth is caused by reduced pup milk intake due to a direct GLP-1 effect or reduced maternal milk production due to decreased caloric intake.

List of excipients
Disodium phosphate dihydrate, propylene glycol, phenol, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment), water for injections.

Incompatibilities
Substances added to Saxenda® may cause degradation of liraglutide. In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Shelf life
30 months

Special precautions for storage
Store in a refrigerator (2°C–8°C). Do not freeze. Store away from the freezer compartment.
After first use: Store below 30°C or store in a refrigerator (2°C–8°C). The product should be discarded 1 month after first use.
Keep the cap on the pen in order to protect from light.

Nature and contents of container
Cartridge (type 1 glass) with a plunger (bromobutyl) and a laminate rubber sheet (bromobutyl/polyisoprene) contained in a pre-filled multidose disposable pen made of polypropylene, polyacetal, polycarbonate and acrylonitrile butadiene styrene.
Each pen contains 3 ml solution and is able to deliver doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg and 3.0 mg. Pack size of 3 pre-filled pens.

HARUS DENGAN RESEP DOKTER
Reg. No.: DKIXXXXXXXXXXX

Special precautions for disposal and other handling
The solution should not be used if it does not appear clear and colourless or almost colourless.
Saxenda® should not be used if it has been frozen.
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. Needles are not included.
The patient should be advised to discard the injection needle after each injection and store the pen without an injection needle attached. This prevents contamination, infection and leakage. It also ensures that the dosing is accurate.
Any unused medicinal product or waste material should be disposed in accordance with local requirements.

Manufactured by:
Novo Nordisk A/S
Novo Allé, DK-2880 Bagsværd, Denmark

Registered by:
PT Beta Pharmacon
Indonesia

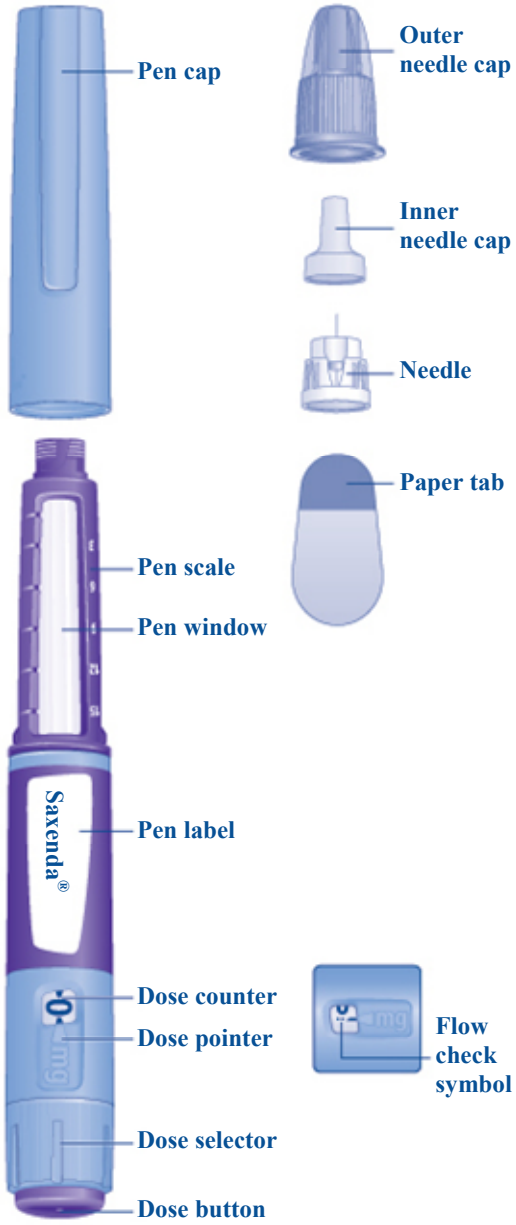
Distributed by:
PT Anugrah Argon Medica
Indonesia

Based on approval date: ……

Saxenda®
6 mg/ml
Solution for injection in pre-filled pen
Liraglutide

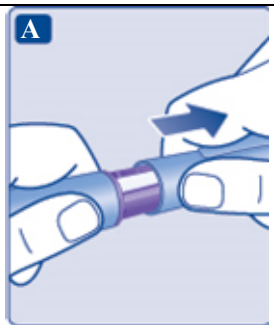
Instructions on how to use Saxenda® 6 mg/ml solution for injection in pre-filled pen **Please read these instructions carefully** before using your Saxenda® pre-filled pen. **Do not use the pen without proper training** from your doctor or nurse. Start by checking your pen to **make sure that it contains Saxenda® 6 mg/ml,** then look at the illustrations below to get to know the different parts of your pen and needle. **If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this pen without help.** Get help from a person with good eyesight who is trained to use the Saxenda® pre-filled pen. Your pen is a pre-filled dial-a-dose pen. It contains 18 mg of liraglutide, and delivers doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg and 3.0 mg. Your pen is designed to be used with NovoFine® or NovoTwist® disposable needles up to a length of 8 mm and as thin as 32G. Needles are not included in the pack. ⚠ **Important information** Pay special attention to these notes as they are important for safe use of the pen.	

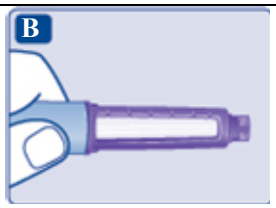
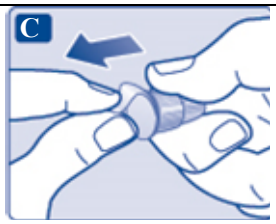
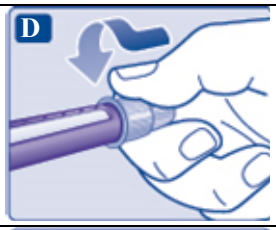
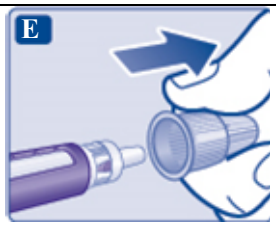
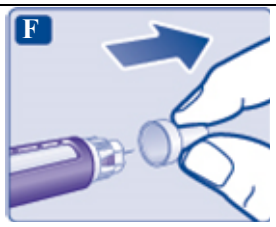
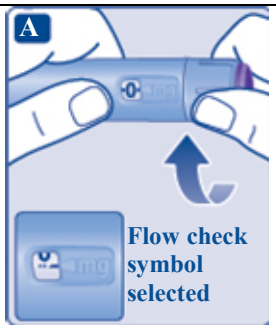
Saxenda® pre-filled pen and needle (example)

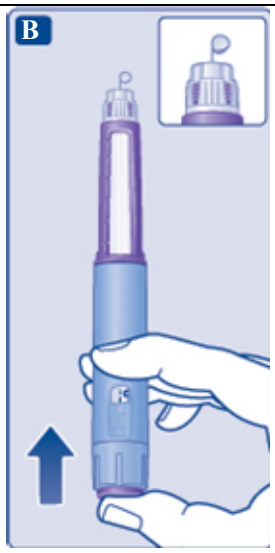
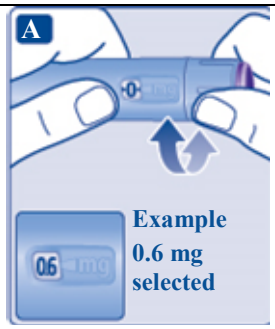


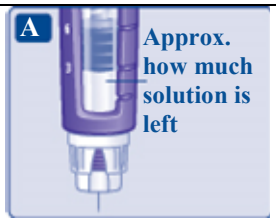
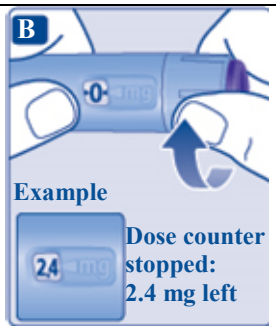
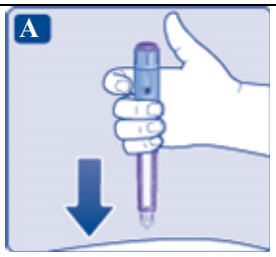
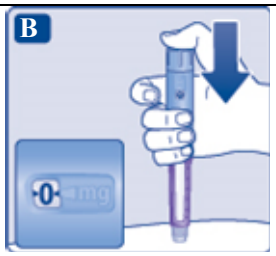
1. Prepare your pen with a new needle

- **Check the name and coloured label** of your pen, to make sure that it contains Saxenda®. This is especially important if you take more than one type of injectable medicine. Using the wrong medicine could be harmful to your health.
- **Pull off the pen cap.**



• **Check that the solution in your pen is clear** and colourless. Look through the pen window. If the solution looks cloudy, do not use the pen.	
• **Take a new needle** and tear off the paper tab.	
• **Push the needle straight onto the pen. Turn until it is on tight.**	
• **Pull off the outer needle cap and keep it for later.** You will need it after the injection, to safely remove the needle from the pen.	
• **Pull off the inner needle cap and throw it away.** If you try to put it back on, you may accidentally stick yourself with the needle. A drop of solution may appear at the needle tip. This is normal, but you must still check the flow, if you use a new pen for the first time. **Do not attach a new needle** to your pen until you are ready to take your injection. ⚠ **Always use a new needle for each injection.** This may prevent blocked needles, contamination, infection and inaccurate dosing. ⚠ **Never use a bent or damaged needle.**	
2. Check the flow • **Before your first injection with each new pen, check the flow.** If your pen is already in use, go to step 3 *Select your dose.* • Turn the dose selector **until the dose counter shows the flow check symbol (▪▪▬).**	

• Hold the pen with the needle pointing up. **Press and hold in the dose button** until the dose counter returns to 0. The 0 must line up with the dose pointer. A drop of solution should appear at the needle tip. A small drop may remain at the needle tip, but it will not be injected. **If no drop appears,** repeat step 2 *Check the flow* up to 6 times. If there is still no drop, change the needle and repeat step 2 *Check the flow* once more. **If a drop still does not appear,** dispose of the pen and use a new one. ⚠ **Always make sure that a drop appears** at the needle tip before you use a new pen for the first time. This makes sure that the solution flows. If no drop appears, you will **not** inject any medicine, even though the dose counter may move. **This may indicate a blocked or damaged needle.** If you do not check the flow before your first injection with each new pen, you may not get the prescribed dose and the intended effect of Saxenda®.	
3. Select your dose • **Turn the dose selector until the dose counter shows your dose (0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg or 3.0 mg).** If you select the wrong dose, you can turn the dose selector forwards or backwards to the correct dose. The pen can dial up to a maximum of 3.0 mg. The dose selector changes the dose. Only the dose counter and dose pointer will show how many mg you select per dose. You can select up to 3.0 mg per dose. When your pen contains less than 3.0 mg the dose counter stops before 3.0 is shown. The dose selector clicks differently when turned forwards, backwards or past the number of mg left. Do not count the pen clicks. ⚠ **Always use the dose counter and the dose pointer to see how many mg you have selected before injecting this medicine.** Do not count the pen clicks. Do not use the pen scale. It only shows approximately how much solution is left in your pen. **Only doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg or 3.0 mg**	

must be selected with the dose selector. The selected dose must line up precisely with the dose pointer to ensure that you get a correct dose.	
How much solution is left? • The **pen scale** shows you **approximately** how much solution is left in your pen.	
• **To see precisely how much solution is left,** use the dose counter: Turn the dose selector until the **dose counter stops.** If it shows 3.0, **at least 3.0 mg** are left in your pen. If the **dose counter stops before 3.0 mg,** there is not enough solution left for a full dose of 3.0 mg. **If you need more medicine than what is left in your pen** Only if trained or advised by your doctor or nurse, you may split your dose between your current pen and a new pen. Use a calculator to plan the doses as instructed by your doctor or nurse. ⚠ **Be very careful to calculate correctly.** If you are not sure how to split your dose using two pens, then select and inject the dose you need with a new pen.	
4. Inject your dose • **Insert the needle into your skin** as your doctor or nurse has shown you. • **Make sure you can see the dose counter.** Do not cover it with your fingers. This could interrupt the injection.	
• **Press and hold down the dose button until the dose counter shows 0.** The 0 must line up with the dose pointer. You may then hear or feel a click.	

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- **Keep the needle in your skin after** the dose counter has returned to 0 and **count slowly to 6.**
- If the needle is removed earlier, you may see a stream of solution coming from the needle tip. If so, the full dose will not be delivered.

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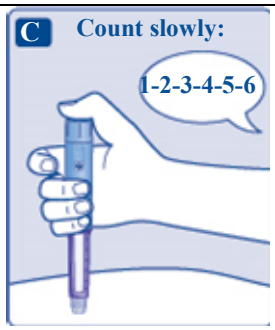
<td> 
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- **Remove the needle from your skin.**
  If blood appears at the injection site, press lightly. Do not rub the area.

  You may see a drop of solution at the needle tip after injecting. This is normal and does not affect your dose.

⚠ **Always watch the dose counter to know how many mg you inject.** Hold the dose button down until the dose counter shows 0.

How to identify a blocked or damaged needle?

- If 0 does not appear in the dose counter after continuously pressing the dose button, you may have used a blocked or damaged needle.
- In this case – you have **not** received **any** medicine – even though the dose counter has moved from the original dose that you have set.

How to handle a blocked needle?
Change the needle as described in step 5 *After your injection* and repeat all steps starting with step 1 *Prepare your pen with a new needle.* Make sure you select the full dose you need.

Never touch the dose counter when you inject. This can interrupt the injection.

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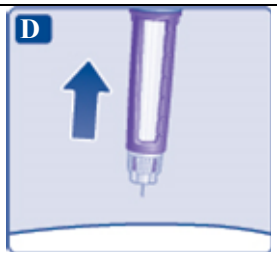
<td> 
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5. After your injection

- **Lead the needle tip into the outer needle cap** on a flat surface without touching the needle or the outer needle cap.

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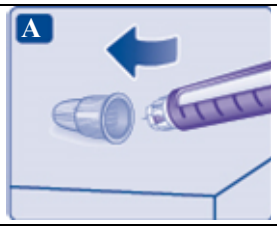
<td> 
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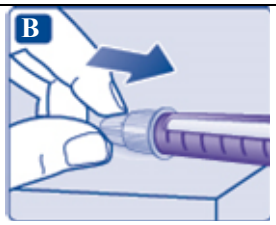
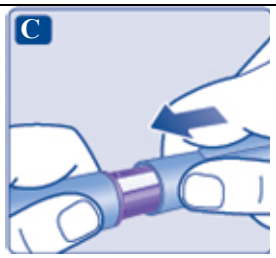
• Once the needle is covered, **carefully push the outer needle cap completely on.** • **Unscrew the needle** and dispose of it carefully.	
• **Put the pen cap on** your pen after each use to protect the solution from light. **Always dispose of the needle after each injection** to ensure convenient injections and prevent blocked needles. If the needle is blocked, you will **not** inject any medicine. When the pen is empty, throw it away **without** a needle on as instructed by your doctor, nurse, pharmacist or local authorities. ⚠ **Never try to put the inner needle cap back on the needle.** You may stick yourself with the needle. ⚠ **Always remove the needle from your pen after each injection.** This may prevent blocked needles, contamination, infection, leakage of solution and inaccurate dosing.	
⚠ **Further important information** • Always keep your pen and needles **out of sight and reach of others,** especially children. • **Never share** your pen or your needles with other people. • Caregivers must **be very careful when handling used needles** to prevent needle injury and cross-infection.	
Caring for your pen • **Do not leave the pen in a car** or other place where it can get too hot or too cold. • **Do not inject Saxenda® which has been frozen.** If you do that, you may not get the intended effect of this medicine. • **Do not expose your pen to dust, dirt or liquid.** • **Do not wash, soak or lubricate your pen.** If necessary, clean it with a mild detergent on a moistened cloth. • **Do not drop your pen** or knock it against hard surfaces. If you drop it or suspect a problem, attach a new needle and check the flow before you inject. • **Do not try to refill your pen.** Once empty, it must be disposed of. • **Do not try to repair your pen** or pull it apart.	

Saxenda®
6 mg/ml
Larutan injeksi dalam pena yang sudah terisi
Liraglutide

Bacalah seluruh bagian brosur ini dengan teliti sebelum Anda mulai menggunakan obat ini karena brosur ini mengandung informasi yang penting untuk Anda.
- Simpan brosur ini. Anda mungkin perlu membacanya lagi.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter, apoteker atau perawat Anda.
- Obat ini telah diresepkan hanya untuk Anda. Jangan memberikannya kepada orang lain. Obat ini mungkin membahayakan mereka, meskipun jika tanda-tanda penyakit mereka sama dengan Anda.
- Jika Anda mengalami efek samping apapun, bicarakan dengan dokter, apoteker atau perawat Anda. Termasuk kemungkinan efek samping apapun yang tidak tercantum dalam brosur ini.

Apa yang terdapat dalam brosur ini

1. Apa itu Saxenda® dan untuk apa kegunaannya

Apa itu Saxenda®
Saxenda® merupakan obat penurun berat badan yang mengandung zat aktif liraglutide. Liraglitude serupa dengan hormon yang diproduksi secara alami yang disebut GLP-1 yang dilepaskan oleh usus setelah makan. Saxenda® bekerja pada reseptor di otak yang mengendalikan nafsu makan, membuat Anda merasa lebih kenyang dan berkurangnya rasa lapar. Obat ini mungkin membantu Anda untuk makan lebih sedikit makanan dan menurunkan berat badan Anda.

Untuk apa kegunaan Saxenda®
Saxenda® digunakan untuk menurunkan berat badan sebagai tambahan dari diet dan olahraga pada orang dewasa dengan usia 18 tahun dan ke atas yang memiliki:
- IMT 30 atau lebih (obesitas), atau
- IMT 27 atau kurang dari 30 (berat badan berlebih) dan gangguan kesehatan yang berhubungan dengan berat badan (seperti diabetes, tekanan darah tinggi, kadar lemak dalam darah yang abnormal atau gangguan pernapasan saat tidur yang disebut ‘apnea tidur obstruktif’).

IMT (Indeks Massa Tubuh) adalah pengukuran berat badan Anda yang berhubungan dengan tinggi badan Anda.

Anda seharusnya hanya melanjutkan menggunakan Saxenda® jika berat badan Anda telah turun setidaknya 5% dari berat badan awal Anda setelah 12 minggu pada dosis 3 mg/hari (lihat bagian 3 *Bagaimana menggunakan Saxenda®*). Konsultasikan dengan dokter Anda sebelum melanjutkan.

Diet dan olahraga
Dokter Anda akan memulai program diet dan olahraga untuk Anda. Tetap jalankan program ini ketika Anda sedang menggunakan Saxenda®.

2. Apa yang Anda perlu ketahui sebelum menggunakan Saxenda®

Jangan menggunakan Saxenda®
- jika Anda alergi terhadap liraglutide atau zat lainnya dalam obat ini (tercantum pada bagian 6 *Isi kemasan dan informasi lainnya*).

Peringatan dan tindakan pencegahan
Bicarakan dengan dokter, apoteker atau perawat Anda sebelum menggunakan Saxenda®.
Penggunaan Saxenda® tidak direkomendasikan jika Anda memiliki gagal jantung yang parah.
Terdapat sedikit pengalaman dengan obat ini pada pasien yang berusia 75 tahun atau 75 tahun ke atas. Obat ini tidak direkomendasikan jika Anda berusia 75 tahun atau 75 tahun ke atas.
Terdapat sedikit pengalaman dengan obat ini pada pasien dengan gangguan ginjal. Jika Anda memiliki penyakit ginjal atau sedang menjalankan dialisis, konsultasikan dengan dokter Anda.
Terdapat sedikit pengalaman dengan obat ini pada pasien dengan gangguan hati. Jika Anda memiliki gangguan hati, konsultasikan dengan dokter Anda.
Obat ini tidak direkomendasikan jika Anda memiliki gangguan lambung atau usus yang parah yang dapat mengakibatkan penundaan pengosongan lambung (disebut gastroparesis), atau jika Anda memiliki penyakit radang usus.

Orang dengan diabetes
Jika Anda memiliki diabetes, jangan menggunakan Saxenda® sebagai pengganti insulin.

Peradangan pankreas
Bicarakan dengan dokter Anda jika Anda mengalami atau pernah mengalami penyakit pada pankreas.

Peradangan kantung empedu dan batu empedu
Jika Anda kehilangan berat badan yang besar, Anda berisiko mengalami batu empedu dan peradangan kantung empedu. Hentikan penggunaan Saxenda® dan segera hubungi dokter jika Anda mengalami nyeri yang parah pada perut bagian atas Anda, biasanya paling parah pada sisi kanan di bawah rusuk. Rasa nyeri dapat dirasakan hingga punggung atau bahu kanan Anda. Lihat bagian 4 *Efek samping yang mungkin dirasakan.*

Penyakit tiroid
Jika Anda memiliki penyakit tiroid, termasuk pembengkakan tiroid dan pembesaran kelenjar tiroid, konsultasikan dengan dokter Anda.

Denyut jantung
Bicarakan dengan dokter Anda jika Anda memiliki palpitasi jantung (Anda merasakan secara sadar detak jantung) atau jika Anda memiliki perasaan detak jantung yang kencang ketika beristirahat selama pengobatan dengan Saxenda®.

Kehilangan cairan dan dehidrasi
Ketika memulai pengobatan dengan Saxenda®, Anda mungkin kehilangan cairan tubuh atau mengalami dehidrasi. Hal tersebut mungkin disebabkan oleh perasaan mual, muntah dan diare. Penting untuk menghindari dehidrasi dengan meminum banyak cairan. Bicarakan dengan dokter, apoteker atau perawat Anda jika Anda memiliki pertanyaan atau kekhawatiran apapun. Lihat bagian 4 *Efek samping yang mungkin dirasakan*

Anak-anak dan remaja
Saxenda® seharusnya tidak digunakan oleh anak-anak dan remaja yang berusia di bawah 18 tahun. Hal tersebut dikarenakan efek dari obat ini belum dipelajari pada kelompok usia ini.

Obat-obatan lain dan Saxenda®
Beritahu dokter, apoteker atau perawat Anda jika Anda sedang menggunakan, baru-baru ini telah menggunakan atau mungkin menggunakan obat lain apapun.
Secara khusus, beritahu dokter, apoteker atau perawat Anda jika:
- Anda sedang menggunakan obat diabetes yang disebut 'sulfonilurea' (seperti glimepiride atau glibenclamide) atau jika Anda sedang menggunakan insulin – Anda mungkin mengalami kadar gula darah rendah (hipoglikemia) ketika menggunakan obat-obat tersebut dengan Saxenda®. Dokter Anda mungkin menyesuaikan dosis dari obat diabetes Anda untuk mencegah Anda mengalami kadar gula darah rendah. Lihat bagian 4 *Efek samping yang mungkin dirasakan* untuk gejala peringatan kadar gula darah rendah. Jika Anda menyesuaikan dosis insulin Anda, dokter Anda mungkin merekomendasikan Anda untuk memantau kadar gula darah Anda lebih sering.
- Anda sedang menggunakan warfarin atau obat-obatan lain yang dikonsumsi melalui mulut yang mengurangi pembekuan darah (antikoagulan). Pemeriksaan darah yang lebih sering untuk menentukan kemampuan darah Anda untuk membeku mungkin diperlukan.

Kehamilan dan menyusui
Jangan menggunakan Saxenda® jika Anda sedang hamil, berpikir bahwa Anda mungkin hamil atau berencana untuk memiliki anak. Hal tersebut dikarenakan belum diketahui apakah Saxenda® mungkin memengaruhi bayi.
Jangan menyusui jika Anda sedang menggunakan Saxenda®. Hal tersebut dikarenakan belum diketahui apakah Saxenda® dapat masuk ke dalam air susu ibu.

Mengemudi dan menggunakan mesin
Saxenda® tidak memengaruhi kemampuan Anda untuk mengemudi dan menggunakan mesin. Jika Anda memerlukan informasi lebih lanjut, bicarakan dengan dokter, apoteker atau perawat Anda.

3. Bagaimana cara menggunakan Saxenda®

Selalu gunakan Saxenda® seperti yang diberitahu oleh dokter Anda. Periksakan dengan dokter, apoteker atau perawat Anda jika Anda tidak yakin.
Dokter Anda akan memulai program diet dan olahraga untuk Anda. Tetap jalankan program ini ketika Anda sedang menggunakan Saxenda®.

Berapa banyak yang disuntikkan
Pengobatan Anda akan dimulai pada dosis yang rendah yang akan ditingkatkan secara bertahap dalam lima minggu pertama pengobatan.
- Ketika Anda pertama kali menggunakan Saxenda®, dosis awal adalah 0,6 mg sekali sehari, untuk setidaknya selama satu minggu.
- Anda seharusnya meningkatkan dosis Anda sebanyak 0,6 mg setiap minggu, hingga Anda mencapai dosis yang direkomendasikan yaitu 3,0 mg sekali sehari.

Dokter Anda akan memberitahu Anda berapa banyak Saxenda® yang akan digunakan setiap minggunya. Biasanya, Anda akan diberitahu untuk mengikuti tabel di bawah ini.

Minggu	**Dosis yang disuntikkan**
Minggu 1	0,6 mg sekali sehari
Minggu 2	1,2 mg sekali sehari
Minggu 3	1,8 mg sekali sehari
Minggu 4	2,4 mg sekali sehari
Minggu 5 dan seterusnya	3,0 mg sekali sehari

Ketika Anda telah mencapai dosis yang direkomendasikan yaitu 3,0 mg pada minggu ke-5 dari pengobatan, tetap gunakan dosis tersebut hingga periode pengobatan Anda berakhir. Jangan meningkatkan dosis Anda lebih banyak lagi.
Dokter Anda akan menilai pengobatan Anda secara teratur.

Bagaimana dan kapan menggunakan Saxenda®
- Sebelum Anda menggunakan pena untuk pertama kalinya, dokter atau perawat Anda akan menunjukkan Anda bagaimana cara menggunakan pena.
- Anda dapat menggunakan Saxenda® kapanpun dalam satu hari, dengan atau tanpa makanan atau minuman.
- Gunakan Saxenda® pada waktu yang sama setiap harinya – pilih waktu yang paling sesuai dengan Anda.

Dimana lokasi penyuntikan
Saxenda® diberikan dengan menyuntikkan di bawah kulit (penyuntikan subkutan).
- Tempat terbaik untuk menyuntikkan adalah di depan pinggang (perut), di depan paha atau lengan bagian atas.
- Jangan menyuntikkan ke dalam pembuluh darah atau otot.

Instruksi penggunaan lebih rinci tersedia pada sisi sebaliknya dari brosur ini.

Orang dengan diabetes
Beritahu dokter Anda jika Anda memiliki diabetes. Dokter Anda mungkin akan menyesuaikan dosis obat diabetes Anda untuk mencegah Anda mengalami kadar gula darah rendah.
- Jangan mencampurkan Saxenda® dengan obat lain yang Anda suntikkan (misalnya insulin).
- Jangan menggunakan Saxenda® dikombinasikan dengan obat yang mengandung agonis reseptor GLP-1 (seperti exenatide atau lixisenatide).

Jika Anda menggunakan Saxenda® lebih dari yang seharusnya
Jika Anda menggunakan Saxenda® melebihi dari yang seharusnya, bicarakan dengan dokter Anda atau segera pergi ke rumah sakit. Bawa kemasan obat bersama Anda. Anda mungkin memerlukan perawatan medis. Berikut efek yang mungkin terjadi:
- Merasa mual
- Muntah.

Jika Anda lupa menggunakan Saxenda®
- Jika Anda melupakan satu dosis dan mengingatnya dalam kurun waktu 12 jam dari waktu biasanya Anda menggunakan satu dosis tersebut, segera suntikkan dosisnya secepatnya setelah Anda ingat.
- Namun, jika lebih dari 12 jam telah berlalu dari waktu dimana Anda seharusnya menggunakan Saxenda®, lewatkan dosis yang terlewat dan suntikkan dosis berikutnya pada hari berikutnya pada waktu biasanya.
- Jangan menggunakan dosis ganda atau meningkatkan dosis pada hari berikutnya untuk mengganti dosis yang terlewat.

Jika Anda berhenti menggunakan Saxenda®
Jangan berhenti menggunakan Saxenda® tanpa bicara dengan dokter Anda.

Jika Anda mempunyai pertanyaan lebih lanjut mengenai penggunaan obat ini, tanyakan pada dokter, apoteker atau perawat Anda.

4. Efek samping yang mungkin dirasakan

Sama seperti semua obat, obat ini dapat menyebabkan efek samping, meskipun tidak semua orang dapat mengalami efek samping tersebut.

Efek samping yang serius
Beberapa reaksi alergi yang parah (anafilaksis) telah dilaporkan jarang terjadi pada pasien yang menggunakan Saxenda®. Anda seharusnya segera menemui dokter Anda jika Anda mengalami gejala seperti gangguan pernapasan, pembengkakan wajah dan tenggorokan serta detak jantung yang cepat.
Kasus peradangan pankreas (pankreatitis) telah dilaporkan tidak umum terjadi pada pasien yang menggunakan Saxenda®. Pankreatitis merupakan kondisi kesehatan yang serius, kondisi medis yang berpotensi mengancam nyawa.

Hentikan penggunaan Saxenda® dan segera hubungi dokter jika Anda mengalami efek samping serius berikut ini:

- Rasa nyeri yang parah dan menetap pada perut (daerah lambung) yang mungkin menjalar ke punggung Anda, dan juga mual dan muntah, yang dapat menjadi suatu tanda peradangan pankreas (pankreatitis).

Efek samping lainnya

Sangat umum: mungkin memengaruhi lebih dari 1 dari 10 orang

- Merasa mual, muntah, diare, konstipasi – biasanya hilang setelah beberapa hari atau minggu.

Umum: mungkin memengaruhi hingga 1 dari 10 orang

- Gangguan yang memengaruhi lambung dan usus, seperti gangguan pencernaan (dispepsia), peradangan lambung (gastritis), ketidaknyamanan lambung, nyeri lambung bagian atas, rasa panas dalam lambung, merasa kembung, buang angin (perut kembung), bersendawa dan mulut kering.
- Merasa lemah atau lelah
- Perubahan indera perasa
- Pusing
- Kesulitan tidur (insomnia). Biasanya terjadi pada 3 bulan pertama pengobatan
- Batu empedu
- Reaksi pada lokasi penyuntikan (seperti memar, nyeri, iritasi, gatal-gatal and ruam)
- Kadar gula darah rendah (hipoglikemia). Tanda peringatan kadar gula darah rendah mungkin muncul secara tiba-tiba dan dapat mencakup: keringat dingin, kulit dingin pucat, sakit kepala, jantung berdetak kencang, merasa sakit, merasa sangat lapar, perubahan penglihatan, merasa mengantuk, merasa lemah, gugup, cemas, bingung, sulit berkonsentrasi dan menggigil (bergemetar). Dokter Anda akan memberitahu bagaimana cara menangani kadar gula darah rendah dan apa yang Anda harus lakukan jika mengalami tanda peringatan tersebut.
- Peningkatan enzim pankreas, seperti lipase dan amilase.

Tidak umum: mungkin memengaruhi hingga 1 dari 100 orang

- Kehilangan cairan (dehidrasi). Hal tersebut lebih sering terjadi pada awal pengobatan dan mungkin disebabkan oleh muntah, mual dan diare
- Penundaan pengosongan lambung
- Peradangan kantung empedu
- Reaksi alergi termasuk ruam kulit
- Merasa tidak sehat secara keseluruhan
- Denyut nadi lebih cepat

Jarang: mungkin memengaruhi hingga 1 dari 1.000 orang

- Pengurangan fungsi ginjal
- Gagal ginjal akut. Tandanya mungkin mencakup pengurangan volume urin, rasa logam di mulut dan mudah memar.

Pelaporan efek samping
Jika terjadi efek samping apapun yang menjadi serius, atau jika Anda mengalami efek samping apapun yang tidak tercantum pada brosur ini, mohon beritahu dokter, perawat atau apoteker Anda.

5. Bagaimana cara menyimpan Saxenda®

Jauhkan obat ini dari penglihatan dan jangkauan anak-anak. Jangan menggunakan Saxenda® setelah tanggal kadaluarsa, yang tercantum pada label pena dan karton setelah 'Expiry'. Tanggal kadaluarsa merujuk pada hari terakhir pada bulan tersebut.

Sebelum penggunaan pertama
Simpan di dalam lemari pendingin (2°C hingga 8°C). Jangan dibekukan. Jauhkan dari kompartemen pembeku.

Setelah Anda mulai menggunakan pena
Anda dapat menyimpan pena hingga 1 bulan ketika disimpan pada suhu di bawah 30°C atau di dalam lemari pendingin (2°C hingga 8°C). Jangan dibekukan. Jauhkan dari kompartemen pembeku. Ketika Anda tidak menggunakan pena, tetap pasang tutup pena untuk melindunginya dari cahaya. Jangan menggunakan obat ini jika larutan tidak jernih dan tak berwarna atau hampir tak berwarna
Jangan membuang obat apapun melalui saluran limbah air atau limbah rumah tangga. Tanyakan kepada apoteker Anda bagaimana cara membuang obat-obatan yang tidak digunakan lagi. Langkah-langkah tersebut akan membantu melindungi lingkungan.

6. Isi kemasan dan informasi lainnya

Apa yang terkandung dalam Saxenda®
- Zat aktifnya adalah liraglutide. Satu ml larutan injeksi mengandung 6 mg liraglutide. Satu pena yang sudah terisi mengandung 18 mg liraglutide.
- Zat lainnya adalah dinatrium fosfat dihidrat, propilen glikol, fenol, asam klorida dan natrium hidroksida (untuk penyesuaian pH) dan air untuk injeksi.

Seperti apa bentuk Saxenda® dan isi kemasan
Saxenda® adalah larutan injeksi yang jernih, tak berwarna atau hampir tak berwarna dalam pena yang sudah terisi. Setiap pena berisi larutan obat sebanyak 3 ml dan dapat memberikan dosis 0,6 mg, 1,2 mg, 1,8 mg, 2,4 mg dan 3,0 mg. Saxenda® tersedia dalam kemasan yang berisi 3 pena.

HARUS DENGAN RESEP DOKTER
Reg. No.: DKIXXXXXXXXXXXX

Diproduksi oleh:
Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd
Denmark

Didaftarkan oleh:
PT Beta Pharmacon
Indonesia

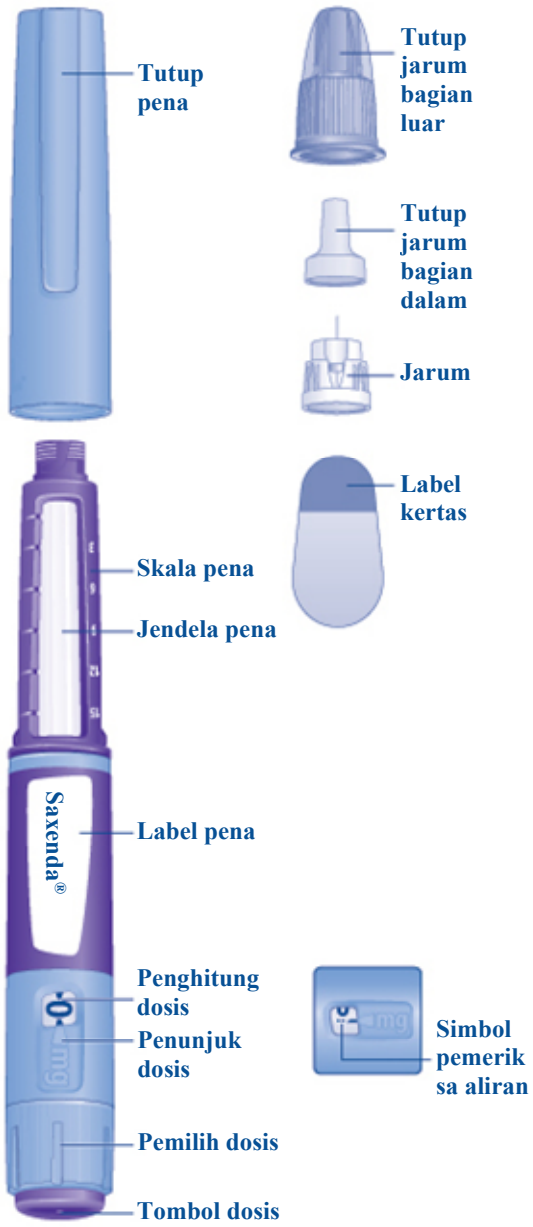
Didistribusikan oleh:
PT Anugrah Argon Medica
Indonesia

Berdasarkan persetujuan tanggal: .....

Saxenda®
6 mg/ml
Larutan injeksi dalam pena yang sudah terisi
Liraglutide

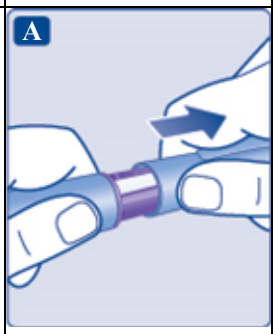
Instruksi bagaimana cara menggunakan Saxenda® larutan injeksi 6 mg/ml dalam pena yang sudah terisi **Bacalah instruksi berikut dengan teliti** sebelum menggunakan Saxenda® dalam pena yang sudah terisi. **Jangan menggunakan pena tanpa pelatihan yang cukup** dari dokter atau perawat Anda. Mulailah dengan memeriksa pena Anda untuk **memastikan bahwa pena berisi Saxenda® 6 mg/ml,** kemudian lihat ilustrasi di bawah ini untuk mengetahui bagian-bagian yang berbeda dari pena dan jarum suntik Anda. **Jika Anda tidak dapat melihat atau memiliki penglihatan yang kurang baik dan tidak dapat membaca penghitung dosis pada pena, jangan menggunakan pena ini tanpa bantuan.** Dapatkan bantuan dari orang yang memiliki penglihatan yang baik yang terlatih menggunakan Saxenda® dalam pena yang telah terisi. Pena Anda merupakan pena yang sudah terisi dengan dosis. Pena berisi 18 mg liraglutide, dan memberikan dosis sebanyak 0,6 mg, 1,2 mg, 1,8 mg, 2,4 mg dan 3,0 mg. Pena Anda dirancang untuk digunakan dengan jarum suntik sekali pakai NovoFine® atau NovoTwist® dengan panjang jarum hingga 8 mm dan setipis 32G. Jarum suntik tidak termasuk dalam kemasan. ⚠ **Informasi penting** Berikan perhatian khusus pada catatan ini, oleh karena hal tersebut penting untuk penggunaan pena yang aman.	

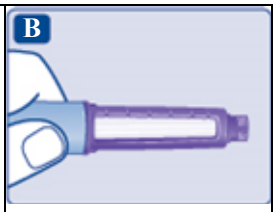
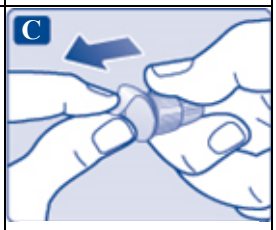
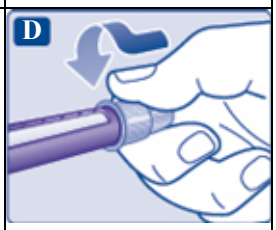
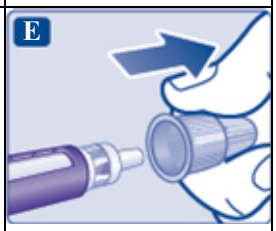
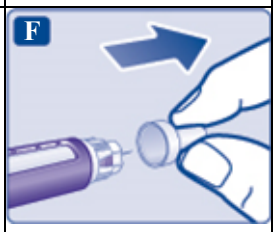
Saxenda® pena yang sudah terisi dan jarum (contoh)

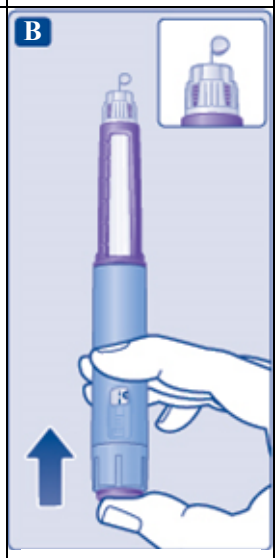
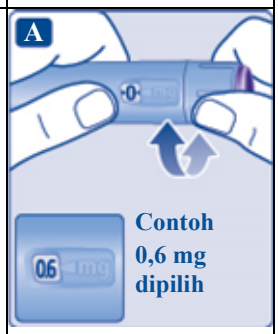


1. Mempersiapkan pena Anda dengan jarum suntik yang baru

- **Periksa nama dan label berwarna** pada pena **Anda,** untuk memastikan bahwa pena berisi Saxenda®. Hal tersebut penting terutama jika Anda menggunakan lebih dari satu jenis obat yang disuntikkan. Penggunaan obat yang salah dapat membahayakan kesehatan Anda
- **Cabut tutup pena.**



• **Periksa bahwa larutan obat di dalam pena Anda jernih dan tidak berwarna**. Lihat melalui jendela pena. Jika larutan obat terlihat keruh, jangan menggunakan pena ini.	
• **Ambil jarum suntik baru** dan lepaskan label kertas.	
• **Dorong jarum suntik lurus ke dalam pena. Putar hingga jarum terpasang erat.**	
• **Cabut tutup jarum bagian luar dan simpan untuk nanti.** Anda akan memerlukannya setelah penyuntikan, untuk mencabut jarum dari pena dengan aman.	
• **Cabut tutup jarum bagian dalam dan buang.** Jika Anda mencoba untuk memasangnya kembali, Anda mungkin akan tertusuk jarum secara tak sengaja. Satu tetes dari larutan obat mungkin muncul pada ujung jarum. Hal tersebut normal, tetapi Anda harus tetap memeriksa alirannya, jika Anda menggunakan pena baru untuk pertama kalinya. **Jangan memasang jarum baru** pada pena Anda hingga Anda siap untuk melakukan penyuntikan ⚠ **Selalu gunakan jarum baru untuk setiap penyuntikan** Hal tersebut dapat mencegah jarum tersumbat, kontaminasi, infeksi dan pengaturan dosis yang tidak akurat ⚠ **Jangan pernah menggunakan jarum yang bengkok atau rusak**	

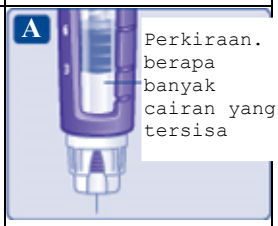
2. Memeriksa aliran • **Sebelum penyuntikan pertama Anda dengan setiap pena baru, periksa alirannya.** Jika pena Anda telah digunakan, lakukan langkah 3 *Pilih dosis Anda.* • Putarkan pemilih dosis **hingga penghitung dosis menunjukkan simbol pemeriksa aliran** ( ).	
• Pegang pena dengan jarum mengarah ke atas **Tekan dan tahan tombol dosis** hingga penghitung dosis kembali ke 0. 0 harus sejajar dengan penunjuk dosis. Setetes larutan obat seharusnya muncul pada ujung jarum. Setetes kecil mungkin tetap pada ujung jarum, tetapi tidak akan disuntikkan. **Jika tetesan tidak muncul,** ulangi langkah 2 *Memeriksa aliran* hingga 6 kali. Jika tetap tidak terdapat tetesan, ganti jarum dan ulangi langkah 2 *Memeriksa aliran* sekali lagi **Jika tetesan tetap tidak muncul,** buang pena dan gunakan yang pena baru. ⚠ **Selalu pastikan bahwa tetesan muncul** pada ujung jarum sebelum Anda menggunakan pena baru untuk pertama kalinya. Hal tersebut untuk memastikan bahwa alirannya lancar. Jika tidak ada tetesan yang muncul, Anda tidak akan menyuntikkan obat apapun, walaupun penghitung dosis mungkin bergerak. **Hal tersebut mungkin mengindikasikan jarum yang tersumbat atau rusak.** Jika Anda tidak memeriksa aliran sebelum penyuntikan pertama Anda dengan setiap pena yang baru, Anda mungkin tidak mendapatkan dosis yang telah diresepkan dan efek yang diinginkan dari Saxenda®.	
3. Memilih dosis Anda • **Putar pemilih dosis hingga penghitung dosis menunjukkan dosis Anda (0,6 mg, 1,2 mg, 1,8 mg, 2,4 mg atau 3,0 mg).** Jika Anda memilih dosis yang salah, Anda dapat memutar pemilih dosis ke depan atau ke belakang untuk dosis yang tepat. Pena dapat memilih hingga dosis maksimum 3.0 mg. Pemilih dosis berguna untuk mengubah dosis. Hanya penghitung dosis dan penunjuk dosis yang akan menunjukkan berapa mg yang Anda pilih per dosis. Anda dapat memilih hingga 3.0 mg per dosis. Ketika pena Anda berisi kurang dari 3.0 mg, penghitung dosis berhenti sebelum	

angka 3,0
Pemilih dosis berbunyi klik secara berbeda ketika diputar ke depan, belakang atau melewati jumlah mg yang tersisa. Jangan menghitung bunyi klik pena.

⚠ **Selalu gunakan penghitung dosis dan penunjuk dosis untuk melihat berapa mg yang Anda telah pilih sebelum menyuntikkan obat ini.**
Jangan menghitung bunyi klik pena.
Jangan menggunakan skala pena. Skala tersebut hanya menunjukkan perkiraan berapa banyak larutan obat yang tersisa dalam pena Anda.
Hanya dosis 0,6 mg, 1,2 mg, 1,8 mg, 2,4 mg, dan 3,0 mg yang harus dipilih dengan pemilih dosis. Dosis yang dipilih harus sejajar secara tepat dengan penunjuk dosis untuk memastikan bahwa Anda mendapatkan dosis yang tepat.

Berapa larutan yang tersisa

- **Skala pena** menunjukkan kepada Anda **perkiraan** berapa banyak larutan yang tersisa dalam pena Anda



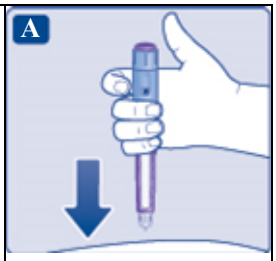
- **Untuk melihat secara tepat berapa banyak larutan yang tersisa,** gunakan penghitung dosis:
Putar pemilih dosis hingga **penghitung dosis berhenti.**
Jika penghitung menunjukkan angka 3,0, **setidaknya 3,0 mg** tersisa dalam pena Anda. Jika **penghitung dosis berhenti sebelum angka 3,0 mg,** tidak terdapat cukup larutan tersisa untuk dosis 3,0 mg penuh.

Jika Anda memerlukan obat lebih dari yang tersisa dalam pena Anda
Hanya jika dilatih atau disarankan oleh dokter atau perawat Anda, Anda mungkin membagi dosis antara pena Anda yang sekarang dan pena yang baru. Gunakan kalkulator untuk merencanakan dosis seperti yang diinstruksikan oleh dokter atau perawat Anda.

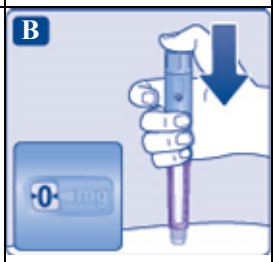
⚠ **Hati-hati untuk menghitung secara tepat**
Jika Anda tidak yakin bagaimana cara membagi dosis menggunakan dua pena, maka pilih dan suntikkan dosis yang Anda perlukan dengan pena yang baru.

4. Menyuntikkan dosis Anda

- **Masukkan jarum ke dalam kulit Anda** seperti yang ditunjukkan oleh dokter atau perawat Anda.
- **Pastikan Anda dapat melihat penghitung dosis.** Jangan menutup penghitung dosis dengan jari Anda. Hal tersebut dapat mengganggu penyuntikan.



- **Tekan dan tahan tombol dosis hingga penghitung dosis menunjukkan 0.** 0 harus sejajar dengan penunjuk dosis. Anda mungkin mendengar atau merasakan bunyi klik.



- **Jaga jarum tetap di dalam kulit Anda** setelah penghitung dosis kembali ke 0 dan **hitung perlahan hingga 6.**
- Jika jarum dilepaskan lebih awal, Anda mungkin melihat aliran larutan datang dari ujung jarum. Jika demikian, dosis penuh tidak akan didapatkan.

- **Cabut jarum dari kulit Anda**
  Jika darah muncul pada lokasi penyuntikan, tekan dengan lembut. Jangan menggosok area penyuntikan.

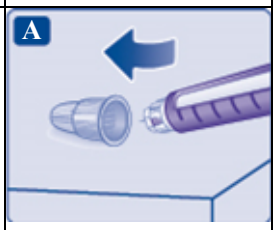
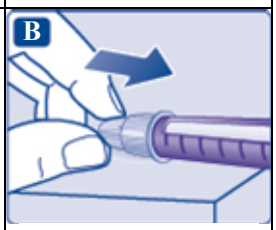
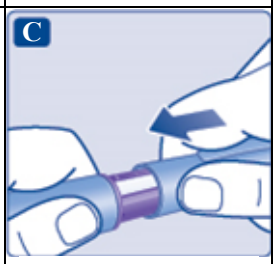
  Anda mungkin melihat tetesan larutan pada ujung jarum setelah penyuntikan. Hal tersebut normal dan tidak memengaruhi dosis Anda.

⚠ **Selalu perhatikan penghitung dosis untuk mengetahui berapa mg yang Anda suntikkan.** Tekan tombol dosis hingga penghitung dosis menunjukkan 0.

Bagaimana cara mengenali jarum yang tersumbat atau rusak

- Jika 0 tidak muncul pada penghitung dosis setelah terus-menerus menekan tombol dosis, Anda mungkin telah menggunakan jarum yang tersumbat atau rusak
- Dalam hal tersebut, Anda **tidak** menerima obat **apapun** - meskipun penghitung dosis telah berpindah dari dosis awal yang telah Anda atur

Bagaimana cara menangani jarum yang tersumbat
Ganti jarum seperti yang dijelaskan pada langkah 5 *Setelah*

penyuntikan Anda dan ulangi semua langkah mulai dari langkah 1 *Mempersiapkan pena Anda dengan jarum yang baru.* Pastikan Anda memilih dosis penuh yang Anda perlukan **Jangan pernah menyentuh penghitung dosis ketika Anda menyuntikkan.** Hal tersebut dapat mengganggu penyuntikan.	
5. Setelah penyuntikan Anda • **Arahkan ujung jarum ke tutup jarum bagian luar** pada permukaan yang datar tanpa menyentuh jarumnya atau tutup jarum bagian luar.	
• Setelah jarum tertutupi, **tekan secara hati-hati tutup jarum bagian luar sepenuhnya.** • **Lepaskan jarum** dan buang secara hati-hati.	
• **Pasang tutup pena** Anda setelah setiap penggunaan untuk melindungi larutan dari cahaya **Selalu buang jarum yang dipakai setelah setiap penyuntikan** untuk memastikan proses penyuntikan yang nyaman dan mencegah jarum yang tersumbat. Jika jarum tersumbat, Anda **tidak** akan menyuntikkan obat apapun Ketika pena kosong, buang pena **tanpa** jarum terpasang seperti yang diinstruksikan oleh dokter, perawat atau apoteker Anda atau aparat setempat Anda. ⚠ **Jangan pernah memasang kembali tutup jarum bagian dalam ke jarum.** Anda mungkin tertusuk jarum. ⚠ **Selalu lepaskan jarum dari pena Anda setelah setiap penyuntikan.** Hal tersebut mungkin mencegah jarum tersumbat, kontaminasi, infeksi, kebocoran larutan dan dosis yang tidak akurat.	
⚠ **Informasi penting lebih lanjut** • Selalu jauhkan pena dan jarum Anda dari **penglihatan dan jangkauan orang lain**, khususnya anak-anak • **Jangan pernah** berbagi pena Anda atau jarum Anda dengan orang lain • Perawat harus **hati-hati ketika menangani jarum yang telah dipakai** untuk mencegah cedera karena jarum dan infeksi silang.	

Pemeliharaan pena Anda • **Jangan meninggalkan pena Anda di dalam mobil** atau tempat lain di mana pena dapat menjadi terlalu panas atau terlalu dingin. • **Jangan menyuntikkan Saxenda® yang telah dibekukan.** Jika Anda melakukan hal tersebut, Anda mungkin tidak dapat memperoleh efek yang diharapkan dari obat ini. • **Jangan biarkan pena Anda terkena debu, kotoran atau cairan.** • **Jangan mencuci, merendam atau melumasi pena Anda.** Jika perlu, bersihkan pena Anda dengan deterjen yang halus pada kain yang telah dilembabkan. • **Jangan menjatuhkan pena Anda** atau membenturkannya pada permukaan yang keras. Jika Anda menjatuhkannya atau menemukan masalah, pasang jarum yang baru dan periksa alirannya sebelum Anda suntikkan. • **Jangan mencoba untuk mengisi ulang pena Anda.** Ketika habis, pena harus dibuang • • **Jangan mencoba untuk memperbaiki pena Anda atau** memisahkan komponen-komponennya.	