

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use SAXENDA® safely and effectively. See full prescribing information for SAXENDA.

SAXENDA (liraglutide) injection, for subcutaneous use
Initial U.S. Approval: 2010

WARNING: RISK OF THYROID C-CELL TUMORS
See full prescribing information for complete boxed warning.

- Liraglutide causes thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether Saxenda causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors has not been determined (5.1).
- Saxenda is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC and the symptoms of thyroid tumors (4, 5.1, 13.1).

-----RECENT MAJOR CHANGES-----

Indications and Usage, Limitations of Use (1).....10/2018

-----INDICATIONS AND USAGE-----

Saxenda is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of

- 30 kg/m² or greater (obese) (1) or
- 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g. hypertension, type 2 diabetes mellitus, or dyslipidemia) (1).

Limitations of Use:

- Saxenda is not indicated for the treatment of type 2 diabetes (1).
- Saxenda should not be used in combination with any other GLP-1 receptor agonist (1).
- Saxenda should not be used with insulin (1, 5.4).
- The safety and efficacy of coadministration with other products for weight loss have not been established (1).

-----DOSAGE AND ADMINISTRATION-----

- Recommended dose of Saxenda is 3 mg daily. Administer at any time of day, without regard to the timing of meals (2).
- Initiate at 0.6 mg per day for one week. In weekly intervals, increase the dose until a dose of 3 mg is reached (2).
- Inject subcutaneously in the abdomen, thigh or upper arm (2).
- The injection site and timing can be changed without dose adjustment (2).

-----DOSAGE FORMS AND STRENGTHS-----

- Injection, pre-filled, multi-dose pen that delivers doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg or 3 mg (6 mg/mL, 3 mL) (3).

-----CONTRAINDICATIONS-----

- Personal or family history of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome type 2 (4, 5.1).
- Hypersensitivity to liraglutide or any product components (4, 5.7).
- Pregnancy (4, 8.1).

-----WARNINGS AND PRECAUTIONS-----

- Thyroid C-cell Tumors: See Boxed Warning (5.1).
- Acute Pancreatitis: Discontinue promptly if pancreatitis is suspected. Do not restart if pancreatitis is confirmed (5.2).
- Acute Gallbladder Disease: If cholelithiasis or cholecystitis are suspected, gallbladder studies are indicated (5.3).
- Serious Hypoglycemia: Can occur when Saxenda is used with an insulin secretagogue (e.g. a sulfonylurea). Consider lowering the dose of anti-diabetic drugs to reduce the risk of hypoglycemia (2, 5.4).
- Heart Rate Increase: Monitor heart rate at regular intervals (5.5).
- Renal Impairment: Has been reported postmarketing, usually in association with nausea, vomiting, diarrhea, or dehydration which may sometimes require hemodialysis. Use caution when initiating or escalating doses of Saxenda in patients with renal impairment (5.6).
- Hypersensitivity Reactions: Postmarketing reports of serious hypersensitivity reactions (e.g., anaphylactic reactions and angioedema). Discontinue Saxenda and other suspect medications and promptly seek medical advice (5.7).
- Suicidal Behavior and Ideation: Monitor for depression or suicidal thoughts. Discontinue Saxenda if symptoms develop (5.8).

-----ADVERSE REACTIONS-----

- Most common adverse reactions, reported in greater than or equal to 5% are: nausea, hypoglycemia, diarrhea, constipation, vomiting, headache, decreased appetite, dyspepsia, fatigue, dizziness, abdominal pain, and increased lipase (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Novo Nordisk Inc. at 1-844-363-4448 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

-----DRUG INTERACTIONS-----

- Saxenda delays gastric emptying. May impact absorption of concomitantly administered oral medications. Use with caution (7).

-----USE IN SPECIFIC POPULATIONS-----

- Pediatric Use: Safety and effectiveness not established and use not recommended (8.4).

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised:10/2018

FULL PRESCRIBING INFORMATION: CONTENTS*
BOXED WARNING: RISK OF THYROID C-CELL TUMORS

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FULL PRESCRIBING INFORMATION

WARNING: RISK OF THYROID C-CELL TUMORS

- **Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether Saxenda causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors has not been determined [see Warnings and Precautions (5.1) and Nonclinical Toxicology (13.1)].**
- **Saxenda is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC with use of Saxenda and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Saxenda [see Contraindications (4), Warnings and Precautions (5.1)].**

1 INDICATIONS AND USAGE

Saxenda is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of

- 30 kg/m² or greater (obese), or
- 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)

Limitations of Use

- Saxenda is not indicated for the treatment of type 2 diabetes mellitus.
- Saxenda and Victoza® both contain the same active ingredient, liraglutide, and therefore should not be used together. Saxenda should not be used in combination with any other GLP-1 receptor agonist.
- Saxenda has not been studied in patients taking insulin. Saxenda and insulin should not be used together [see Warnings and Precautions (5.4)].
- The safety and effectiveness of Saxenda in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.

2 DOSAGE AND ADMINISTRATION

The recommended dosage of Saxenda is 3 mg daily. The dose escalation schedule in Table 1 should be used to reduce the likelihood of gastrointestinal symptoms. If patients do not tolerate an increased dose during dose escalation, consider delaying dose escalation for approximately one additional week. Saxenda should be discontinued, however, if a patient cannot tolerate the 3 mg dose, as efficacy has not been established at lower doses (0.6, 1.2, 1.8, and 2.4 mg).

Table 1. Dose Escalation Schedule

Week	Daily Dose
1	0.6 mg
2	1.2 mg
3	1.8 mg
4	2.4 mg
5 and onward	3 mg

Saxenda should be taken once daily at any time of day, without regard to the timing of meals. Saxenda can be injected subcutaneously in the abdomen, thigh, or upper arm. The injection site and timing can be changed without dose adjustment. Saxenda must not be administered intravenously or intramuscularly.

When initiating Saxenda in patients taking insulin secretagogues (such as sulfonylureas), consider reducing the dose of the insulin secretagogue (for example, by one-half) to reduce the risk for hypoglycemia, and monitor blood glucose. Saxenda and insulin should not be used together [see *Warnings and Precautions (5.4) and Adverse Reactions (6.1)*]. Conversely, if discontinuing Saxenda in patients with type 2 diabetes, monitor for an increase in blood glucose.

Evaluate the change in body weight 16 weeks after initiating Saxenda and discontinue Saxenda if the patient has not lost at least 4% of baseline body weight, since it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

If a dose is missed, the once-daily regimen should be resumed as prescribed with the next scheduled dose. An extra dose or increase in dose should not be taken to make up for the missed dose. If more than 3 days have elapsed since the last Saxenda dose, patients should reinitiate Saxenda at 0.6 mg daily and follow the dose escalation schedule in Table 1, which may reduce the occurrence of gastrointestinal symptoms associated with reinitiation of treatment.

Prior to initiation of Saxenda, patients should be trained by their healthcare professional on proper injection technique. Training reduces the risk of administration errors such as needle sticks and incomplete dosing. Refer to the accompanying Instructions for Use for complete administration instructions with illustrations.

Saxenda solution should be inspected prior to each injection, and the solution should be used only if it is clear, colorless, and contains no particles.

BMI is calculated by dividing weight in (kilograms) by height (in meters) squared. A chart for determining BMI based on height and weight is provided in Table 2.

Table 2. BMI Conversion Chart

Weight	(lb)	125	130	135	140	145	150	155	160	165	170	175	180	185	190	195	200	205	210	215	220	225	
	(kg)	56.8	59.1	61.4	63.6	65.9	68.2	70.5	72.7	75.0	77.3	79.5	81.8	84.1	86.4	88.6	90.9	93.2	95.5	97.7	100.0	102.3	
Height																							
(in)	(cm)																						
58	147.3	26	27	28	29	30	31	32	34	35	36	37	38	39	40	41	42	43	44	45	46	47	
59	149.9	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	43	44	45	46	
60	152.4	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	
61	154.9	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	
62	157.5	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	38	39	40	41	41	
63	160.0	22	23	24	25	26	27	28	28	29	30	31	32	33	34	35	36	36	37	38	39	40	
64	162.6	22	22	23	24	25	26	27	28	28	29	30	31	32	33	34	34	35	36	37	38	39	
65	165.1	21	22	23	23	24	25	26	27	28	28	29	30	31	32	33	33	34	35	36	37	38	
66	167.6	20	21	22	23	23	24	25	26	27	27	28	29	30	31	32	32	33	34	35	36	36	
67	170.2	20	20	21	22	23	24	24	25	26	27	27	28	29	30	31	31	32	33	34	35	35	
68	172.7	19	20	21	21	22	23	24	24	25	26	27	27	28	29	30	30	31	32	33	34	34	
69	175.3	18	19	20	21	21	22	23	24	24	25	26	27	27	28	29	30	30	31	32	33	33	
70	177.8	18	19	19	20	21	22	22	23	24	24	25	26	27	27	28	29	29	30	31	32	32	
71	180.3	17	18	19	20	20	21	22	22	23	24	24	25	26	27	27	28	29	29	30	31	31	
72	182.9	17	18	18	19	20	20	21	22	22	23	24	24	25	26	27	27	28	29	29	30	31	
73	185.4	17	17	18	19	19	20	20	21	22	22	23	24	24	25	26	26	27	28	28	29	30	
74	188.0	16	17	17	18	19	19	20	21	21	22	23	23	24	24	25	26	26	27	28	28	29	
75	190.5	16	16	17	18	18	19	19	20	21	21	22	23	23	24	24	25	26	26	27	28	28	
76	193.0	15	16	16	17	18	18	19	20	20	21	21	22	23	23	24	24	25	26	26	27	27	

3 DOSAGE FORMS AND STRENGTHS

Solution for subcutaneous injection, pre-filled, multi-dose pen that delivers doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg, or 3 mg (6 mg/mL, 3 mL).

4 CONTRAINDICATIONS

Saxenda is contraindicated in:

- Patients with a personal or family history of medullary thyroid carcinoma (MTC) or patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) [see *Warnings and Precautions (5.1)*].
- Patients with a prior serious hypersensitivity reaction to liraglutide or to any of the product components [see *Warnings and Precautions (5.7)*].
- Pregnancy [see *Use in Specific Populations (8.1)*].

5 WARNINGS AND PRECAUTIONS

5.1 Risk of Thyroid C-cell Tumors

Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors (adenomas and/or carcinomas) at clinically relevant exposures in both genders of rats and mice [see *Nonclinical Toxicology (13.1)*]. Malignant thyroid C-cell carcinomas were detected in rats and mice. It is unknown whether Saxenda will cause thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors has not been determined.

Cases of MTC in patients treated with liraglutide have been reported in the postmarketing period; the data in these reports are insufficient to establish or exclude a causal relationship between MTC and liraglutide use in humans.

Saxenda is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2. Counsel patients regarding the potential risk for MTC with the use of Saxenda and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness).

Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Saxenda. Such monitoring may increase the risk of unnecessary procedures, due to low test specificity for serum calcitonin and a high background incidence of thyroid disease. Significantly elevated serum calcitonin may indicate MTC, and patients with MTC usually have calcitonin values greater than 50 ng/L. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated.

5.2 Acute Pancreatitis

Based on spontaneous postmarketing reports, acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with liraglutide. After initiation of Saxenda, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, Saxenda should promptly be discontinued and appropriate management should be initiated. If pancreatitis is confirmed, Saxenda should not be restarted.

In Saxenda clinical trials, acute pancreatitis was confirmed by adjudication in 9 (0.3%) of 3291 Saxenda-treated patients and 2 (0.1%) of 1843 placebo-treated patients. In addition, there were 2 cases of acute pancreatitis in Saxenda-treated patients who prematurely withdrew from these clinical trials, occurring 74 and 124 days after the last dose. There were 2 additional cases in Saxenda-treated patients, 1 during an off-treatment follow-up period within 2 weeks of discontinuing Saxenda, and 1 that occurred in a patient who completed treatment and was off-treatment for 106 days.

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