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·····

Dosage and Administration (2.2)……..06/2022
Contraindications (4)……06/2022

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

Pediatric patients aged 12 years and older with:

- body weight above 60 kg and
- an initial BMI corresponding to 30 kg/m^2 for adults (obese) by international cut-offs (1).

Limitations of Use:

- SAXENDA contains liraglutide and should not be coadministered with other liraglutide-containing products or with any other GLP-1 receptor agonist (1).
- The safety and effectiveness of SAXENDA in pediatric patients with type 2 diabetes have not been established (1).
- The safety and efficacy of SAXENDA in combination with other products intended for weight loss have not been established (1).

·····DOSAGE AND ADMINISTRATION·····

- Inject SAXENDA subcutaneously in the abdomen, thigh, or upper arm once daily at any time of day, without regard to the timing of meals (2.2).
- The recommended dose of SAXENDA is 3 mg daily (2.3).
- Initiate at 0.6 mg per day for one week. In weekly intervals, increase the dose until a dose of 3 mg is reached (2.3).
- If pediatric patients do not tolerate an increased dose during dose escalation, the dose may also be lowered to the previous level. Dose escalation for pediatric patients may take up to 8 weeks (2.3).
- Pediatric patients who do not tolerate 3 mg daily may have their dose reduced to 2.4 mg daily (2.3).
- Adult patients with type 2 diabetes should monitor blood glucose prior to starting SAXENDA and during SAXENDA treatment (2.3).

·····DOSAGE FORMS AND STRENGTHS·····

- Injection: 6 mg/mL solution in a 3 mL pre-filled, single-patient-use pen that delivers doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg or 3 mg (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 excipients in SAXENDA (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).
- Hypoglycemia: Can occur in adults when SAXENDA is used with an insulin secretagogue (e.g. a sulfonylurea) or insulin. The risk may be lowered by a reduction in the dose of concomitantly administered insulin secretagogues or insulin. In the pediatric clinical trial, patients did not have type 2 diabetes. Hypoglycemia occurred in SAXENDA-treated pediatric patients. Inform all patients of the risk of hypoglycemia and educate them on the signs and symptoms 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, diarrhea, constipation, vomiting, injection site reactions, headache, hypoglycemia, dyspepsia, fatigue, dizziness, abdominal pain, increased lipase, upper abdominal pain, pyrexia, and gastroenteritis (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).

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 06/2022

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

*Sections or subsections omitted from the full prescribing information are not listed.

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 *[see Dosage and Administration (2.1)]*:
  - 30 kg/m^2 or greater (obese), or
  - 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)

- Pediatric patients aged 12 years and older with:
  - body weight above 60 kg and
  - an initial BMI corresponding to 30 kg/m^2 or greater for adults (obese) by international cut-offs (Cole Criteria, Table 2) *[see Dosage and Administration (2.1)]*

Limitations of Use

- SAXENDA contains liraglutide and should not be coadministered with other liraglutide-containing products or with any other GLP-1 receptor agonist.
- The safety and effectiveness of SAXENDA in pediatric patients with type 2 diabetes have not been established.
- 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 ADMINISTRATIONPatient Selection

Select patients for SAXENDA treatment as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management based on the BMI values provided in Tables 1 and 2.

Adult and Pediatric Patients

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 1.

Table 1: 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	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43
62	157. 5	23	24	25	26	27	27	28	29	30	31	32	33	34	35	36	37	38	38	39	40	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

Pediatric Patients Aged 12 Years and Older

BMI cut-offs for obesity in pediatric patients aged 12 years and older are presented in Table 2.

Table 2: International Obesity Task Force BMI Cut-offs for Obesity by Sex and Age for Pediatric Patients Aged 12 Years and Older (Cole Criteria)

Age (years)	Body mass index 30 kg/m^2	
	Males	Females
12	26.02	26.67
12.5	26.43	27.24
13	26.84	27.76
13.5	27.25	28.20
14	27.63	28.57
14.5	27.98	28.87
15	28.30	29.11
15.5	28.60	29.29
16	28.88	29.43
16.5	29.14	29.56
17	29.41	29.69
17.5	29.70	29.84

2.2 Important Administration Instructions

- Prior to initiation of SAXENDA, train patients on proper injection technique. Refer to the accompanying Instructions for Use for complete administration instructions with illustrations.
- Inspect SAXENDA visually prior to each injection. Only use if solution is clear, colorless, and contains no particles.
- Inject SAXENDA subcutaneously once daily at any time of day, without regard to the timing of meals.
- Inject SAXENDA subcutaneously in the abdomen, thigh, or upper arm. No dose adjustment is needed if

- Rotate injection sites within the same region in order to reduce the risk of cutaneous amyloidosis *[see Adverse Reactions (6.2)]*.
- If a dose is missed, resume the once-daily regimen as prescribed with the next scheduled dose. Do not administer an extra dose or increase the dose to make up for the missed dose.
- If more than 3 days have elapsed since the last SAXENDA dose, reinitiate SAXENDA at 0.6 mg daily and follow the dose escalation schedule in Table 3, to reduce the occurrence of gastrointestinal adverse reactions associated with reinitiation of treatment.

2.3 Dosage in Adults and Pediatric Patients Aged 12 Years and Older

- Initiate SAXENDA with a dose of 0.6 mg daily for one week. Then follow the dose escalation schedule in Table 3 to minimize gastrointestinal adverse reactions *[see Adverse Reactions (6.1)]*.

Table 3: 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

Adult Patients

- For adults, the recommended dosage of SAXENDA is 3 mg daily, lower doses are for titration only.
- Discontinue SAXENDA if the patient cannot tolerate the 3 mg dose.
- If patients do not tolerate an increased dose during dose escalation, consider delaying dose escalation for approximately one additional week.
- 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.
- In adult patients with type 2 diabetes, monitor blood glucose prior to starting SAXENDA and during SAXENDA treatment.

Pediatric Patients

- For pediatric patients, the recommended maintenance dosage of SAXENDA is 3 mg daily. Pediatric patients who do not tolerate 3 mg daily may have their maintenance dose reduced to 2.4 mg daily. Discontinue SAXENDA if the patient cannot tolerate the 2.4 mg dose.
- If pediatric patients do not tolerate an increased dose during dose escalation, the dose may also be lowered to the previous level. Dose escalation for pediatric patients may take up to 8 weeks.
- Evaluate the change in BMI after 12 weeks on the maintenance dose and discontinue SAXENDA if the patient has not had a reduction in BMI of at least 1% from baseline, since it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

3 DOSAGE FORMS AND STRENGTHS

Injection: 6 mg/mL clear, colorless solution in a 3 mL pre-filled, single-patient-use pen that delivers doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg, or 3 mg.

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)]*.

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