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APPLICATION NUMBER:

206321Orig1s000

LABELING

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 [rDNA origin] injection), solution for subcutaneous use
Initial U.S. Approval: 2014

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 risk of MTC and the symptoms of thyroid tumors (4, 5.1, 13.1).

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 effects of Saxenda on cardiovascular morbidity and mortality have not been established (1).
- The safety and efficacy of coadministration with other products for weight loss have not been established (1).
- Saxenda has not been studied in patients with a history of pancreatitis (1, 5.2).

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

- 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) (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: Counsel patients regarding the risk of medullary thyroid carcinoma and the symptoms of thyroid tumors (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 1-877-484-2869 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

- Nursing Mothers: Discontinue drug or nursing (8.3).
- Pediatric Use: Safety and effectiveness not established and use not recommended (8.4).

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 12/2014

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

1	INDICATIONS AND USAGE
2	DOSAGE AND ADMINISTRATION
3	DOSAGE FORMS AND STRENGTHS
4	CONTRAINDICATIONS
5	WARNINGS AND PRECAUTIONS
	5.1 Risk of Thyroid C-cell Tumors
	5.2 Acute Pancreatitis
	5.3 Acute Gallbladder Disease
	5.4 Risk for Hypoglycemia with Concomitant Use of Anti-Diabetic Therapy
	5.5 Heart Rate Increase
	5.6 Renal Impairment
	5.7 Hypersensitivity Reactions
	5.8 Suicidal Behavior and Ideation
6	ADVERSE REACTIONS
	6.1 Clinical Trials Experience
	6.2 Postmarketing Experience
7	DRUG INTERACTIONS
	7.1 Oral Medications
8	USE IN SPECIFIC POPULATIONS
	8.1 Pregnancy
	8.3 Nursing Mothers
	8.4 Pediatric Use
	8.5 Geriatric Use
	8.6 Renal Impairment
	8.7 Hepatic Impairment

8.8	Gastroparesis
10	OVERDOSAGE
11	DESCRIPTION
12	CLINICAL PHARMACOLOGY
	12.1 Mechanism of Action
	12.2 Pharmacodynamics
	12.3 Pharmacokinetics
13	NONCLINICAL TOXICOLOGY
	13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
14	CLINICAL STUDIES
16	HOW SUPPLIED/STORAGE AND HANDLING
	16.1 How Supplied
	16.2 Recommended Storage
17	PATIENT COUNSELING INFORMATION
	17.1 FDA-Approved Medication Guide
	17.2 Instructions
	17.3 Risk of Thyroid C-cell Tumors
	17.4 Acute Pancreatitis
	17.5 Acute Gallbladder Disease
	17.6 Hypoglycemia in Patients with Type 2 Diabetes Mellitus on Anti-Diabetic Therapy
	17.7 Heart Rate Increase
	17.8 Dehydration and Renal Impairment
	17.9 Hypersensitivity Reactions
	17.10 Suicidal Behavior and Ideation
	17.11 Jaundice and Hepatitis
	17.12 Never Share a Saxenda Pen Between Patients

*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 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 effects of Saxenda on cardiovascular morbidity and mortality 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.
- Saxenda has not been studied in patients with a history of pancreatitis [see Warnings and Precautions (5.2)].

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.

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