Limitations of Use

Saxenda® (liraglutide) injection 3 mg is indicated 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 (eg, hypertension, type 2 diabetes mellitus, or dyslipidemia)
- Pediatric patients aged 12 years and older with BMI corresponding to 30 kg/m² or greater for body weight above 60 kg (132 lbs) and initial dyslipidemia

The safety and effectiveness of Saxenda® in any other GLP-1 receptor agonist. Saxenda® contains liraglutide and should not be coadministered with other liraglutide-containing products or with other GLP-1 receptor agonist.

Indications and Usage

Saxenda® (liraglutide) injection 3 mg is indicated as an adjunct to a reduced-calorie diet and increased physical activity, and can help patients lose weight and keep it off.1

More than 1.5 million patients have used Saxenda® globally.2

Patient profile

Identify and support patients with obesity who may benefit from Saxenda®

Consider Saxenda® for chronic weight management. Combined with a reduced-calorie meal plan and increased physical activity, Saxenda® can help patients lose weight and keep it off.1

Important Safety 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. 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 the uncertain value for early detection of MTC in patients treated with Saxenda®.

Important Safety Information (cont’d)

Contraindications
Saxenda® is contraindicated in:
- Patients with a personal or family history of MTC or patients with MEN 2.
- Patients with a prior serious hypersensitivity reaction to liraglutide or to any of the excipients in Saxenda®.
- Pregnancy.

For frustrated patients like Roberto, diet and exercise may not be enough because obesity is impacted by hormones. But it can be hormonally treated.

Similar to native GLP-1, Saxenda® works in the brain to decrease hunger, increase satiety, and thereby reduce food intake.1,3

For frustrated patients like Roberto, diet and exercise may not be enough because obesity is impacted by hormones. But it can be hormonally treated.

Similar to native GLP-1, Saxenda® works in the brain to decrease hunger, increase satiety, and thereby reduce food intake.1,3

Please see additional Important Safety Information throughout.

Please click here for Prescribing Information, including Boxed Warning.
85% of patients treated with Saxenda® lost some weight\(^1\)

In a 1-year clinical trial, the majority of patients achieved clinically meaningful weight loss of \(\geq 5\%\) with Saxenda\(^1\)

In a 56-week study of 3,731 patients without type 2 diabetes and with a BMI \(\geq 30\), or \(\geq 27\) with at least 1 weight-related comorbidity, patients were randomized to either Saxenda\(^\circledR\) (n=2,487) or placebo (n=1,244), with all patients receiving a reduced-calorie diet (~500 kcal/day deficit) and physical activity counseling.

85% of patients treated with Saxenda\(^\circledR\) lost some weight\(^1\)

In a 1-year clinical trial, the majority of patients achieved clinically meaningful weight loss of \(\geq 5\%\) with Saxenda\(^1\)

### Safety and tolerability of Saxenda\(^\circledR\) were evaluated in 5 clinical studies\(^1\)

Adverse reactions, in studies up to 56 weeks, reported in \(\geq 2\%\) of adult patients treated with Saxenda\(^\circledR\) and more frequently than with placebo\(^1\)

<table>
<thead>
<tr>
<th></th>
<th>Placebo (n=1,244)</th>
<th>Saxenda(^\circledR) (n=3,384)</th>
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<tr>
<td><strong>GASTROINTESTINAL DISORDERS</strong></td>
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</tr>
<tr>
<td>Nausea</td>
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<td>39.3</td>
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<tr>
<td>Diarrhea</td>
<td>9.9</td>
<td>20.9</td>
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<tr>
<td>Constipation</td>
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<tr>
<td>Vomiting</td>
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<tr>
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<tr>
<td>Upper Abdominal Pain</td>
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<td>Gastroesophageal Reflux Disease</td>
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<tr>
<td>Abdominal Distension</td>
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<tr>
<td>Eructation</td>
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<td>Flatulence</td>
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<tr>
<td>Dry Mouth</td>
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<tr>
<td><strong>METABOLISM &amp; NUTRITION DISORDERS</strong></td>
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<tr>
<td>Hypoglycemia in Type 2 Diabetes(^a)</td>
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<tr>
<td><strong>NERVOUS SYSTEM DISORDERS</strong></td>
<td></td>
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<td>Headache</td>
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<tr>
<td><strong>GENERAL DISORDERS &amp; ADMINISTRATION SITE CONDITIONS</strong></td>
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<td></td>
</tr>
<tr>
<td>Injection Site Reaction(^b)</td>
<td>10.5</td>
<td>13.9</td>
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<tr>
<td>Fatigue</td>
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<tr>
<td>Asthenia</td>
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<tr>
<td><strong>INFECTIONS &amp; INFESTATIONS</strong></td>
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<tr>
<td>Gastroenteritis</td>
<td>3.2</td>
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<td>Urinary Tract Infection</td>
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<td>Increased Lipase</td>
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<tr>
<td><strong>PSYCHIATRIC DISORDERS</strong></td>
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<tr>
<td>Insomnia</td>
<td>1.7</td>
<td>2.4</td>
</tr>
<tr>
<td>Anxiety</td>
<td>1.6</td>
<td>2.0</td>
</tr>
</tbody>
</table>

\(^a\)Defined as blood glucose <54 mg/dL with or without symptoms of hypoglycemia in patients with type 2 diabetes not on concomitant insulin (Study 2).

\(^b\)The most common reactions, each reported by 1% to 2.5% of Saxenda\(^\circledR\)-treated patients and more commonly than by placebo-treated patients, included erythema, pruritus, and rash at the injection site.

See more about how patients achieved and maintained weight loss at year 3 at [SaxendaPro.com](http://SaxendaPro.com).

Learn more about safety and tolerability, including tips for how patients can manage their GI side effects at [SaxendaPro.com](http://SaxendaPro.com).

\(\text{GI, gastrointestinal.}\)

### Important Safety Information (cont’d)

#### Warnings and Precautions

- **Risk of Thyroid C-cell Tumors:** 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.

Please see additional Important Safety Information throughout.

Please [click here](http://clickhere) for Prescribing Information, including Boxed Warning.
Robust clinical trial program

Study 1 (1-year)\textsuperscript{1,5}
- Results from a 56-week, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of Saxenda®
- Patients with type 2 diabetes and a BMI \(\geq 30\), or \(\geq 27\) with at least 1 additional comorbidity, were randomized to receive once-daily Saxenda® (n=635) or placebo (n=633) in conjunction with a lifestyle modification program that included increased physical activity and a 500-kcal/day deficit diet
- Patients were first treated with a low-calorie diet (total energy intake: 1,200-1,400 kcal/day) and with increased physical activity in the run-in period lasting up to 12 weeks. Patients who lost at least 5% of screening body weight during the run-in period were randomized, then underwent a 4-week dose-escalation period followed by 52 weeks on the full dose
- The primary end points were mean percent weight change, percentage of patients achieving 5% of baseline weight loss, and percentage of patients achieving \(\geq 10\) % of baseline weight loss at 56 weeks
- Secondary end points included changes in waist circumference, blood pressure, and lipids
- Mean baseline body weight was 233.0 lb and mean BMI was 38.3 kg/m\(^2\)

Study 2 (1-year)\textsuperscript{1,4}
- Results from a 56-week, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of Saxenda®
- Patients with type 2 diabetes and a BMI \(\geq 30\), or \(\geq 27\) with at least 1 additional comorbidity, were randomized to receive once-daily Saxenda® (n=423) or placebo (n=421), in conjunction with a lifestyle modification program that included increased physical activity and a 500-kcal/day deficit diet
- Patients who lost at least 5% of screening body weight from randomization to week 56 were randomized to receive once-daily Saxenda® (n=421) or placebo (n=420) in conjunction with a lifestyle modification program that included increased physical activity and a 500-kcal/day deficit diet
- Patients were randomized, then underwent a 4-week dose-escalation period followed by 52 weeks on the full dose
- The primary end points were mean percent weight change, percentage of patients achieving 5% of baseline weight loss, and percentage of patients achieving \(\geq 10\) % of baseline weight loss at 56 weeks
- Secondary end points included changes in waist circumference, blood pressure, and lipids
- Mean baseline body weight was 233.9 lb and mean BMI was 38.8 kg/m\(^2\)

Study 3
- Results from a 56-week, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of Saxenda®
- Patients with a BMI \(\geq 30\), or \(\geq 27\) with 1 or more weight-related comorbidities (N=422) were randomized to receive once-daily Saxenda® (n=212) or placebo (n=210) in conjunction with a lifestyle modification program that included increased physical activity and a 500-kcal/day-deficit diet
- Patients were first treated with a low-calorie diet (total energy intake: 1,200-1,400 kcal/day) and with increased physical activity in the run-in period lasting up to 12 weeks. Patients who lost at least 5% of screening body weight during the run-in period were randomized, then underwent a 4-week dose-escalation period followed by 52 weeks on the full dose
- The primary end points were mean percent weight change from randomization to week 56, percentage of patients not gaining more than 0.5% body weight from randomization to week 56, and percentage of patients achieving \(\geq 5\) % weight loss from randomization to week 56
- Patients were not to have an A1C of 7% to 10% and be treated with metformin, a sulfonylurea, or a glitazone as a single agent or in any combination, or with diet and exercise alone
- Mean baseline body weight was 219.1 lb and mean BMI was 35.6 kg/m\(^2\)

Important Safety Information (cont’d)

Warnings and Precautions (cont’d)
- **Acute Pancreatitis:** Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with liraglutide postmarketing. Observe patients carefully for signs and symptoms of pancreatitis (persistent severe abdominal pain, sometimes radiating to the back with or without vomiting). If pancreatitis is suspected, discontinue Saxenda® promptly and if pancreatitis is confirmed, do not restart.

Selected Important Safety Information

**Indications and Usage**

Saxenda® (liraglutide) injection 3 mg 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/m\(^2\) or greater (obese) or 27 kg/m\(^2\) or greater (overweight) in the presence of at least one weight-related comorbidity (eg, hypertension, type 2 diabetes mellitus, or dyslipidemia)
- Pediatric patients aged 12 years and older with body weight above 60 kg (132 lbs) and initial BMI corresponding to 30 kg/m\(^2\) or greater for adults (obese) by international cut-offs

**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.

**Important Safety 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. 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 (eg, 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®.

**Contraindications**

Saxenda® is contraindicated in:
- Patients with a personal or family history of MTC or patients with MEN 2.
- Patients with a prior serious hypersensitivity reaction to liraglutide or to any of the excipients in Saxenda®.
- Pregnancy.

**Warnings and Precautions**

**Risk of Thyroid C-cell Tumors:** 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.
Selected Important Safety Information (cont’d)

• Acute Gallbladder Disease: Substantial or rapid weight loss can increase the risk of cholelithiasis; however, the incidence of acute gallbladder disease was greater in patients treated with Saxenda® than with placebo even after accounting for the degree of weight loss. If cholelithiasis is suspected, gallbladder studies and appropriate clinical follow-up are indicated.

• Hypoglycemia: Adult patients with type 2 diabetes on an insulin secretagogue (eg, a sulfonylurea) or insulin may have an increased risk of hypoglycemia, including severe hypoglycemia with use of Saxenda. The risk may be lowered by a reduction in the dose of insulin secretagogues or insulin. In pediatric patients without type 2 diabetes, hypoglycemia occurred. Inform all patients of the risk of hypoglycemia and educate them on the signs and symptoms.

• Heart Rate Increase: Mean increases in resting heart rate of 2 to 3 beats per minute (bpm) were observed in patients treated with Saxenda®. Monitor heart rate at regular intervals and inform patients to report palpitations or feelings of a racing heartbeat while at rest during treatment with Saxenda®. Discontinue Saxenda® in patients who experience a sustained increase in resting heart rate.

• Renal Impairment: Acute renal failure and worsening of chronic renal failure, which may sometimes require hemodialysis, have been reported, usually in association with nausea, vomiting, diarrhea, or dehydration. Use caution when initiating or escalating doses of Saxenda® in patients with renal impairment.

• Hypersensitivity Reactions: Serious hypersensitivity reactions (eg, anaphylaxis and angioedema) have been reported in patients treated with liraglutide. If a hypersensitivity reaction occurs, patients should stop taking Saxenda® and promptly seek medical advice.

• Suicidal Behavior and Ideation: In adult clinical trials, 9 (0.3%) of 3,384 patients treated with Saxenda® and 2 (0.1%) of the 1,941 treated with placebo reported suicidal ideation; one of the Saxenda® treated patients attempted suicide. In a pediatric trial, 10 (0.8%) of the 125 Saxenda® treated patients died by suicide. There was insufficient information to establish a causal relationship to Saxenda®. Monitor patients for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Discontinue treatment if patients experience suicidal thoughts or behaviors. Avoid Saxenda® in patients with a history of suicidal attempts or active suicidal ideation.

Adverse Reactions

• The most common adverse reactions, reported in ≥5% are nausea, diarrhea, constipation, vomiting, injection site reactions, headache, hypoglycemia, dyspepsia, fatigue, dizziness, abdominal pain, increased lipase, upper abdominal pain, pyrexia, and gastroenteritis.

Drug Interactions

• Saxenda® causes a delay of gastric emptying and has the potential to impact the absorption of concomitantly administered oral medications. Monitor for potential consequences of delayed absorption of oral medications concomitantly administered with Saxenda®.

Use in Specific Populations

• There are no data on the presence of liraglutide in human breast milk; liraglutide was present in the milk of lactating rats.

• Saxenda® has not been studied in patients less than 12 years of age.

• Saxenda® slows gastric emptying. Saxenda® has not been studied in patients with preexisting gastroparesis.

Please click here for Prescribing Information, including Boxed Warning.

Simplifying coverage verification and the PA process

Prescribe Saxenda® in just 3 steps

STEP 1: VERIFY PHARMACY BENEFITS IN MINUTES

• Visit SaxendaCoverage.com to find out your patient’s coverage and estimated OOP costs
• Benefit verification takes only minutes to complete. Results will provide patient OOP pre- and post-savings programs at their preferred pharmacy
• You can also call the NovoCare® (1-888-809-3942) 8:00 AM to 8:00 PM ET, M-F

Coverage requests

If your patient is not covered for Saxenda® DO NOT start the PA process. Instead, talk to your patient about contacting the benefits manager in his or her Human Resources department.

STEP 2: FASTER PAs, OFTEN IN REAL TIME

• Novo Nordisk partners with CoverMyMeds® to help you navigate the PA process

www.covermymeds.com

1-866-452-5017

Benefits of CoverMyMeds®

• Process requests for any medication and all plans
• Receive faster PA determinations, often in real time
• Create PA revaluations from previously submitted requests
• Available at no cost to providers and staff
• Integrates with 500+ EHRs

STEP 3: PRESCRIBE SAXENDA® AND ACTIVATE A SAVINGS CARD

• Prescribe Saxenda® (and the NovoFine® 32G Tip needles, if necessary)
• Give your patient a Saxenda® Sample Kit, which includes a Saxenda® Savings Card, and a Saxenda® Patient Brochure
• Please contact your Novo Nordisk sales representative to receive a Patient Sample Kit
• Direct your patient to visit Saxenda.com to obtain and/or activate a Saxenda® Savings Card prior to heading to the pharmacy
• Patient’s may pay as little as $25 per 30-day Saxenda® prescription. Maximum benefit of $200 per prescription, with 12 benefits annually. Eligibility and other restrictions apply. Novo Nordisk reserves the right to modify or cancel this program at any time
• When your patient activates a Saxenda® Savings Card online at Saxenda.com, they will automatically be enrolled in SaxendaCare®

EHR, electronic health record; OOP, out of pocket; PA, prior authorization.

Please click here for Prescribing Information, including Boxed Warning.


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