When it comes to losing weight and keeping it off

# WE HAVE THE **NOW YOU CAN GIVE US THE**

Give them the power to choose a way forward by adding Saxenda<sup>®</sup>

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



More than **1.5 million** patients have used Saxenda<sup>®</sup> globally<sup>2,a</sup>

#### **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<sup>2</sup> or greater (obese) or 27 kg/m<sup>2</sup> or greater (overweight) in the presence of at least one weight-related comorbid condition (eq, 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<sup>2</sup> or greater for adults (obese) by international cut-offs

#### Limitations of Use

- Saxenda<sup>®</sup> 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<sup>®</sup> 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.

#### <sup>a</sup>As of March 2020.

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<sup>®</sup> 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<sup>®</sup>.

**Important Safety Information** 

Please see additional Important Safety Information throughout.

Please click here for Prescribing Information, including Boxed Warning.



### Patient profile

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

		Roberto	BMI: 33	
	Actor Portrayal.	Age: Height: Weight: Comorbidities: Waist circumference: Weight-loss attempts:	38 years old 6'0" 245 lb High cholesterol 41" 5 attempts	
		• Former athlete who used to have no problem staying in shape		
		<ul> <li>Goes to the gym 4 times a week and follows a reduced-calorie meal plan</li> </ul>		
		• Frustrated because, even though he's trying ha than ever before, the weight just won't stay off		
		<ul> <li>Feels hungry constantly, so he believes that he reducing his caloric intake but is disappointed his lack of progress</li> </ul>		
		<b>Personal goal:</b> To be able to keep up with the younger guys at the precinct and stay active in h day-to-day role		

#### 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<sup>a</sup> to decrease hunger, increase satiety, and thereby reduce food intake<sup>1,3</sup>



• GLP-1 is a native hormone that is released in response to food intake and acts as a physiological regulator of appetite<sup>1,4</sup>

Saxenda<sup>®</sup> is 97% similar to native GLP-1<sup>1</sup>

<sup>a</sup>Shown in animal models.

BMI, body mass index; GLP-1, glucagon-like peptide 1.

#### Important Safety Information (cont'd) Contraindications

Saxenda<sup>®</sup> 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<sup>®</sup>.
- Pregnancy.



- ugh he's trying harder ust won't stay off
- believes that he's is disappointed with

eep up with the nd stay active in his

# 85% of patients treated with Saxenda $^{\mbox{\tiny B}}$ lost some weight $^{\mbox{\tiny 1}}$

## In a 1-year clinical trial, the majority of patients achieved clinically meaningful weight loss of $\geq 5\%$ with Saxenda $^{\otimes 1}$

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<sup>®</sup> (n=2,487) or placebo (n=1,244), with all patients receiving a reduced-calorie diet (~500 kcal/day deficit) and physical activity counseling.



Saxenda<sup>®</sup> 3 mg (n=2,487) + diet and exercise

Placebo (n=1,244) + diet and exercise

<sup>a</sup>Difference from placebo (least squares [LS] mean, 27.9% [95% CI, 23.9, 31.9]). <sup>b</sup>Difference from placebo (LS mean, 18.5% [95% CI, 15.2, 21.7]). <sup>c</sup>Weight loss in pounds (lb) calculated as 5%, 10%, or 20% of mean baseline body weight.

- The primary end points were mean percentage weight change, percentage of patients achieving ≥5% of baseline weight loss, and percentage of patients achieving >10% of baseline weight loss
- Weight loss was defined as any reduction in weight from start of trial
- Mean baseline body weight was 233.9 lb, and mean baseline BMI was 38.3 kg/m<sup>2</sup>

## See more about how patients achieved and maintained weight loss at year 3 at **SaxendaPro.com**.

Please see additional Important Safety Information throughout. Please <u>click here</u> for Prescribing Information, including Boxed Warning.

# Safety and tolerability of Saxenda<sup>®</sup> were evaluated in 5 clinical studies<sup>1</sup>

### Adverse reactions, in studies up to 56 weeks, reported in $\ge 2\%$ of adult patients treated with Saxenda<sup>®</sup> and more frequently than with placebo<sup>1</sup>

	Placebo (n=1,941)	Saxenda <sup>®</sup> (n=3,384)	
	%	%	
GASTROINTESTINAL DISORDERS			
Nausea	13.8	39.3	
Diarrhea	9.9	20.9	
Constipation	8.5	19.4	
Vomiting	3.9	15.7	
Dyspepsia	2.7	9.6	
Abdominal Pain	3.1	5.4	
Upper Abdominal Pain	2.7	5.1	
Gastroesophageal Reflux Disease	1.7	4.7	
Abdominal Distension	3.0	4.5	
Eructation	0.2	4.5	
Flatulence	2.5	4.0	
Dry Mouth	1.0	2.3	
METABOLISM & NUTRITION DISORDERS			
Hypoglycemia in Type 2 Diabetes <sup>a</sup>	6.6	12.6	
NERVOUS SYSTEM DISORDERS			
Headache	12.6	13.6	
Dizziness	5.0	6.9	
GENERAL DISORDERS & ADMINISTRATION SITE CONDITIONS			
Injection Site Reaction <sup>b</sup>	10.5	13.9	
Fatigue	4.6	7.5	
Asthenia	0.8	2.1	
INFECTIONS & INFESTATIONS			
Gastroenteritis	3.2	4.7	
Urinary Tract Infection	3.1	4.3	
Viral Gastroenteritis	1.6	2.8	
INVESTIGATIONS			
Increased Lipase	2.2	5.3	
PSYCHIATRIC DISORDERS			
Insomnia	1.7	2.4	
Anxiety	1.6	2.0	

<sup>a</sup>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).

<sup>b</sup>The most common reactions, each reported by 1% to 2.5% of Saxenda<sup>®</sup>-treated patients and more commonly than by placebo-treated patients, included erythema, pruritus, and rash at the injection site.

## Learn more about safety and tolerability, including tips for how patients can manage their GI side effects at <u>SaxendaPro.com</u>.

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.

### Robust clinical trial program

#### Study 1 (1-year)<sup>1,5</sup>

- Results from a 56-week, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of Saxenda®
- Patients with a BMI ≥30, or ≥27 with 1 or more weightrelated comorbidities (N=3,731) were randomized to receive once-daily Saxenda® (n=2,487) or placebo (n=1,244) in conjunction with a lifestyle modification program that included increased physical activity and a 500-kcal/day deficit diet
- Patients underwent a 4-week dose-escalation period followed by 52 weeks on the full dose

#### Study 1 (3-year)<sup>1,6</sup>

• Results from a 160-week randomized,

- double-blind, placebo-controlled study to evaluate the long-term safety and efficacy of Saxenda®
- Patients with pre-diabetes and with a BMI of either ≥30, or ≥27 with at least 1 additional comorbidity, were randomized to receive once-daily Saxenda® (n=1,505) or placebo (n=749) in conjunction with a lifestyle modification program that included increased physical activity and a 500-kcal/day deficit diet
- Study 2<sup>1,7</sup>
- Results from a 56-week, randomized,
- double-blind, placebo-controlled study to evaluate the safety and efficacy of Saxenda<sup>®</sup> The primary end points were mean percent weight change, percentage of patients achieving ≥5% of
- Patients with type 2 diabetes with a BMI ≥27 (N=635) were randomized to receive once-daily Saxenda<sup>®</sup> (n=423) or placebo (n=212), 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

#### Study 3<sup>1,8</sup>

- Results from a 56-week, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of Saxenda®
- Patients with a BMI ≥30, or ≥27 with 1 or more weightrelated 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 500kcal/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

#### 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.

- The primary end points were mean percent weight change, percentage of patients achieving ≥5% of baseline weight loss, and percentage of patients achieving >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 38.3 kg/m<sup>2</sup>
- Patients with type 2 diabetes were excluded from participating
- Patients underwent a 4-week dose-escalation period followed by 156 weeks on the full dose, with a 12-week off-drug observational follow-up period
- The study evaluated percentage of patients achieving weight loss of at least 5% of body weight at both 1 year and 3 years
- Mean baseline body weight was 236.7 lb and mean BMI was 38.8 kg/m<sup>2</sup>
- The primary end points were mean percent weight change, percentage of patients achieving ≥5% of baseline weight loss, and percentage of patients achieving >10% of baseline weight loss at 56 weeks
   Mean baseline body weight was 233.0 lb and mean BMI
- was 37.1 kg/m<sup>2</sup>
- Patients were 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

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 ≥5% weight loss from randomization to week 56
- $\bullet$  Mean baseline body weight was 219.1 lb and mean BMI was 35.6  $kg/m^2$
- Patients with type 2 diabetes were excluded from participating

## Indications and Usage

Saxenda<sup>®</sup> (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<sup>2</sup> or greater (obese) or 27 kg/m<sup>2</sup> 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 body weight above 60 kg (132 lbs) and initial BMI corresponding to 30 kg/m<sup>2</sup> or greater for adults (obese) by international cut-offs

#### **Limitations of Use**

• Saxenda<sup>®</sup> contains liraglutide and should not be coadministered with other liraglutide-containing products or with any other GLP-1 receptor agonist.

Selected Important Safety Information

- The safety and effectiveness of Saxenda® in pediatric patients with type 2 diabetes have not been established.
- The safety and effectiveness of Saxenda<sup>®</sup> 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<sup>®</sup>.
- 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.

Saxenda<sup>®</sup> liraglutide injection 3mg

## 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<sup>®</sup> 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 secretagoque (eq, 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<sup>®</sup>. 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<sup>®</sup>. Discontinue Saxenda<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> and 2 (0.1%) of the 1,941 treated with placebo reported suicidal ideation; one of the Saxenda<sup>®</sup> treated patients attempted suicide. In a pediatric trial, 1(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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>.

#### **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<sup>®</sup> has not been studied in patients less than 12 years of age.
- Saxenda<sup>®</sup> slows gastric emptying. Saxenda<sup>®</sup> has not been studied in patients with preexisting gastroparesis.

## 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 postsavings 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<sup>®</sup> to help you navigate the PA process

www.covermvmeds.com

-866-452-5017

- Benefits of CoverMyMeds®
- Process requests for any medication and all plans
- Receive faster PA determinations, often in real time
- Create PA renewals 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<sup>®</sup> (and the NovoFine<sup>®</sup> 32G Tip needles, if necessary)
- Give your patient a Saxenda<sup>®</sup> Sample Kit, which includes a Saxenda<sup>®</sup> 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<sup>®</sup> Savings Card prior to heading to the pharmacy
  - Patients 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.

References: 1. Saxenda [package insert]. Plainsboro, NJ: Novo Nordisk Inc; 2020. 2. Data on file. Novo Nordisk Inc; Plainsboro, NJ. 3. Flint A, Raben A, Astrup A, Holst JJ. Glucagon-like peptide 1 promotes satiety and suppresses energy intake in humans. J Clin Invest. 1998; 101(3):515-520. 4. Orskov C, Wettergren A, Holst JJ. Secrétion of the incretin hormones glucagon-like peptide-1 and gastric inhibitory polypeptide correlates with insulin secretion of the interest hormones glucagon-like peptide-1 and gastric inhibitory polypeptide correlates with insulin secretion in normal man throughout the day. *Scand J Gastroenterol*. 1996;31(7):665-670. **5**. Pi-Sunyer X, Astrup A, Fujioka K, et al. A randomized, controlled trial of 3.0 mg of liraglutide in weight management. *N Engl J Med*. 2015;373(1):11-22. **6**. le Roux CW, Astrup A, Fujioka K, et al; SCALE Obesity and Prediabetes NN8022-1839 Study Group. 3 years of liraglutide versus placebo for type 2 diabetes risk reduction and weight management in individuals with prediabetes: a randomised, double-blind trial. Lancet. 2017;389(10077):1399-1409. 7. Davies MJ, Bergenstal R, Bode B, et al; NN8022-1922 Study Group. Efficacy of liraglutide for weight loss among patients with type 2 diabetes: the SCALE diabetes randomized clinical trial. JAMA. 2015:314(7):687-699. 8. Wadden TA. Hollander P. Klein S. et al. Weight maintenance and additional weight loss with liraglutide after low-calorie-diet-induced weight loss: the SCALE Maintenance randomized study. Int J Obes (Lond). 2013;37(11):1443-1451.



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BN 400426 POR: 54 GBP: EC20020009 ID: 0000000

Saxenda<sup>®</sup> Savings Card

n benefit of \$200 per prescription and 12 benefits an Elisibility and other restrictions apply.

ordisk reserves the right to modify or cancel this program at any time.

Saxenda

Pay as little as \$25 or save up to \$200 per Saxenda® press

