

## Saxenda® (liraglutide [rDNA origin] injection) Fact Sheet



### Product Description

Saxenda® (liraglutide [rDNA origin] injection) is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to a low-calorie meal plan and increased physical activity for **chronic weight management** in adults with an initial body mass index (BMI) of 30 or greater (obese), or 27 or greater (overweight) in the presence of at least one weight-related comorbid condition, such as hypertension, dyslipidemia, or type 2 diabetes.<sup>1</sup>

Saxenda®, when used in combination with a low-calorie meal plan and increased physical activity, has been shown to help a majority of patients achieve clinically meaningful weight loss,<sup>a</sup> as demonstrated in a 1-year clinical study.<sup>1</sup>

Saxenda® is 97% similar to naturally occurring GLP-1, which is a physiological regulator of appetite and caloric intake. Like native GLP-1, Saxenda® activates areas of the brain involved in appetite regulation, decreasing caloric intake and lowering body weight.<sup>1</sup>

The recommended dose of Saxenda® is 3 mg daily. It may be administered at any time, without regard to timing of meals. It is injected subcutaneously in the abdomen, thigh, or upper arm.<sup>1</sup>

Saxenda® was approved by the US Food and Drug Administration (FDA) in December 2014.

As of February 2016, Saxenda® has been commercially launched in the United States, Canada, and Denmark. It has also been approved in the European Union, Mexico, and Australia. Please refer to local labels for more information.

### Indications and Usage

#### What is Saxenda®?

Saxenda® is an injectable prescription medicine that may help some adults with excess weight (BMI  $\geq 27$ ) who also have weight-related medical problems or obesity (BMI  $\geq 30$ ), lose weight and keep the weight off. Saxenda® should be used with a reduced-calorie meal plan and increased physical activity.

- Saxenda® is not for the treatment of type 2 diabetes
  - Saxenda® and Victoza® have the same active ingredient, liraglutide, and should not be used together
  - Saxenda® should not be used with other GLP-1 receptor agonist medicines
  - Saxenda® and insulin should not be used together
  - It is not known if Saxenda® is safe and effective when taken with other prescription, over-the-counter, or herbal weight-loss products
  - It is not known if Saxenda® changes your risk of heart problems or stroke or of death due to heart problems or stroke
  - It is not known if Saxenda® can be used safely in people who have had pancreatitis
  - It is not known if Saxenda® is safe and effective in children under 18 years of age.
- Saxenda® is not recommended for use in children

**Please see Important Safety Information throughout. Please click [here](#) for Prescribing Information.**

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<sup>a</sup> Weight loss of 5% to 10% has been shown to be clinically meaningful.

## Important Safety Information

### What is the most important information I should know about Saxenda® (liraglutide [rDNA origin] injection)?

Serious side effects may happen in people who take Saxenda®, including:

- 1. Possible thyroid tumors, including cancer.** During the drug testing process, the medicine in Saxenda® caused rats and mice to develop tumors of the thyroid gland. Some of these tumors were cancers. It is not known if Saxenda® will cause thyroid tumors or a type of thyroid cancer called medullary thyroid cancer in people. If medullary thyroid cancer occurs, it may lead to death if not detected and treated early. If you develop tumors or cancer of the thyroid, your thyroid may have to be surgically removed.
  - Before you start taking Saxenda®, tell your health care professional if you or any of your family members have had thyroid cancer, especially medullary thyroid cancer, or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Do not take Saxenda® if you or any of your family members have medullary thyroid cancer, or if you have MEN 2. People with these conditions already have a higher chance of developing medullary thyroid cancer in general and should not take Saxenda®
  - While taking Saxenda®, tell your health care professional if you get a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath. These may be symptoms of thyroid cancer
- 2. Inflammation of the pancreas (pancreatitis),** which may be severe and lead to death.
  - **Before taking Saxenda®, tell your health care professional if you have had:** pancreatitis, stones in your gallbladder (gallstones), a history of alcoholism, or high blood triglyceride levels. These medical conditions can make you more likely to get pancreatitis in general. It is not known if having these conditions will lead to a higher chance of getting pancreatitis while taking Saxenda®
  - **While taking Saxenda®:** Stop taking Saxenda® and call your health care professional right away if you have pain in your stomach area (abdomen) that is severe and will not go away. The pain may happen with or without vomiting. The pain may be felt going from your abdomen through to your back. This type of pain may be a symptom of pancreatitis

### Who should not use Saxenda®?

#### Do not use Saxenda® if:

- you or any of your family members have a history of medullary thyroid cancer
- you have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). This is a disease where people have tumors in more than one gland in their body
- you are allergic to liraglutide or any of the ingredients in Saxenda®. Symptoms of a serious allergic reaction may include: swelling of your face, lips, tongue, or throat, fainting or feeling dizzy, very rapid heartbeat, problems breathing or swallowing, and severe rash or itching. Talk with your health care professional if you are not sure if you have any of these conditions
- are pregnant or planning to become pregnant. Saxenda® may harm your unborn baby

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## **What should I tell my health care professional before using Saxenda® (liraglutide [rDNA origin] injection)?**

Before taking Saxenda®, tell your health care professional if you:

- have any of the conditions listed in the section “What is the most important information I should know about Saxenda®?”
- are taking certain medications called GLP-1 receptor agonists
- are allergic to liraglutide or any of the other ingredients in Saxenda®
- have severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems with digesting food
- have or have had kidney or liver problems
- have or have had depression or suicidal thoughts
- have any other medical conditions
- are pregnant or plan to become pregnant. Saxenda® may harm your unborn baby. Tell your health care professional if you become pregnant while taking Saxenda®. If you are pregnant you should stop using Saxenda®
- are breastfeeding or plan to breastfeed. It is not known if Saxenda® passes into your breast milk. You and your health care professional should decide if you will take Saxenda® or breastfeed. You should not do both without talking with your health care professional first

Tell your health care professional about all the medicines you take including prescription and nonprescription medicines, vitamins, and herbal supplements. Saxenda® slows stomach emptying and can affect medicines that need to pass through the stomach quickly. Saxenda® may affect the way some medicines work and some other medicines may affect the way Saxenda® works. Tell your health care professional if you take diabetes medicines, especially sulfonylurea medicines or insulin.

Know the medicines you take. Keep a list of them with you to show your health care professional and pharmacist each time you get a new medicine.

### **How should I use Saxenda®?**

- Inject your dose of Saxenda® under the skin (subcutaneous injection) in your stomach area (abdomen), upper leg (thigh), or upper arm, as instructed by your health care professional.  
**Do not inject into a vein or muscle**
- Never share your Saxenda® pen or needles with another person. You may give an infection to them, or get an infection from them

### **What are the possible side effects of Saxenda®?**

**Saxenda® may cause serious side effects, including:**

- **possible thyroid tumors, including cancer**
- **inflammation of the pancreas (pancreatitis)**
- **gallbladder problems.** Saxenda® may cause gallbladder problems including gallstones. Some gallbladder problems need surgery. Call your health care professional if you have any of the following symptoms: pain in your upper stomach (abdomen), fever, yellowing of your skin or eyes (jaundice), and clay-colored stools

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- **low blood sugar (hypoglycemia) in people with type 2 diabetes who also take medicines to treat type 2 diabetes.** Saxenda® (liraglutide [rDNA origin] injection) can cause low blood sugar in people with type 2 diabetes who also take medicines used to treat type 2 diabetes (such as sulfonylureas). In some people, the blood sugar may get so low that they need another person to help them. If you take a sulfonylurea medicine, the dose may need to be lowered while you use Saxenda®. Signs and symptoms of low blood sugar may include: shakiness, sweating, headache, drowsiness, weakness, confusion, irritability, hunger, fast heartbeat, feeling jittery, and dizziness. You should check your blood sugar before you start taking Saxenda® and while you take Saxenda®
- **increased heart rate.** Saxenda® can increase your heart rate while you are at rest. Your health care professional should check your heart rate while you take Saxenda®. Tell your health care professional if you feel your heart racing or pounding in your chest and it lasts for several minutes when taking Saxenda®
- **kidney problems (kidney failure).** Saxenda® may cause nausea, vomiting, or diarrhea leading to loss of fluids (dehydration). Dehydration may cause kidney failure, which can lead to the need for dialysis. This can happen in people who have never had kidney problems before. Drinking plenty of fluids may reduce your chance of dehydration. Call your health care professional right away if you have nausea, vomiting, or diarrhea that does not go away, or if you cannot drink liquids by mouth
- **serious allergic reactions.** Serious allergic reactions can happen with Saxenda®. Stop using Saxenda®, and get medical help right away if you have any symptoms of a serious allergic reaction
- **depression or thoughts of suicide.** You should pay attention to any mental changes, especially sudden changes, in your mood, behaviors, thoughts, or feelings. Call your health care professional right away if you have any mental changes that are new, worse, or worry you

Common side effects of Saxenda® include nausea, diarrhea, constipation, low blood sugar (hypoglycemia), vomiting, headache, decreased appetite, upset stomach, tiredness, dizziness, stomach pain, and changes in enzyme (lipase) levels in your blood. Nausea is most common when first starting Saxenda®, but decreases over time in most people as their body gets used to the medicine. Tell your health care professional if you have any side effect that bothers you or that does not go away.

Please click [here](#) for Prescribing Information.

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1. Saxenda [package insert]. Plainsboro, NJ: Novo Nordisk Inc; 2015.