

Package leaflet: Information for the user

Lyxumia™ 10 micrograms solution for injection

Lyxumia™ 20 micrograms solution for injection

lixisenatide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Lyxumia is and what it is used for
2. What you need to know before you use Lyxumia
3. How to use Lyxumia
4. Possible side effects
5. How to store Lyxumia
6. Contents of the pack and other information

1. What Lyxumia is and what it is used for

Pharmacotherapeutic group

Lyxumia contains the active substance lixisenatide.

It is an injectable medicine used to help your body to control your blood sugar level when it is too high. It is used in adults with type 2 diabetes.

Therapeutic indications

Lyxumia is used with other medicines for diabetes when they are not enough to control your blood sugar levels. These may include: – oral antidiabetics (such as metformin, pioglitazone, sulphonylurea medicines) and/ or , – a basal insulin, a type of insulin which works all day.

2. What you need to know before you use Lyxumia

Contraindications

Do not use Lyxumia:

- if you are allergic to lixisenatide or any of the other ingredients of this medicine (listed in section 6).

Appropriate precautions for use; special warnings

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Lyxumia if:

- you have type 1 diabetes or diabetic ketoacidosis (a complication of diabetes that occurs when the body is unable to break down glucose because there is not enough insulin) since this medicine will not be right for you
- you have signs of severe inflammation of the pancreas (acute pancreatitis), such as severe stomach (abdominal) pain which does not goes away
- you have ever had inflammation of the pancreas (pancreatitis)
- you have a severe stomach or gut problem such as a disease of the muscles of the stomach called “gastroparesis” which results in delayed stomach emptying
- you have severe kidney disease or you are on dialysis as the use of this medicine will not be recommended
- you are also taking a sulphonylurea or a basal insulin. This is because low blood sugar (hypoglycaemia) can occur. Your doctor may want to control your blood sugar level and then, decide to reduce your dose of basal insulin or sulphonylurea. Lyxumia should not be used with a combination of both basal insulin and sulphonylurea
- you are taking other medicines, as there are other medicines such as antibiotics or stomach resistant tablets or capsules that should not stay too long in your stomach (see section Other medicines and Lyxumia)
- you experience loss of fluids/dehydration, e.g. in case of vomiting, nausea and diarrhoea. It is important to avoid dehydration by drinking plenty of fluids, especially when starting treatment with Lyxumia
- you suffer from heart problems which can cause shortness of breath or ankle swelling, since there is limited experience in this population.

Children and adolescents

There is no experience with Lyxumia in children and adolescents less than 18 years and therefore, the use of Lyxumia is not recommended in this age group.

Other medicines and Lyxumia

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines.

The effect of some medicines you swallow might be affected by Lyxumia. Some medicines such as antibiotics or stomach resistant tablets or capsules that should not stay too long in your stomach may need to be taken at least one hour before or four hours after your Lyxumia injection.

Pregnancy and breast-feeding

Lyxumia should not be used during pregnancy. It is not known if Lyxumia may harm your unborn child.

Lyxumia should not be used if breast-feeding. It is not known if Lyxumia passes into your milk.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

If you use Lyxumia with a sulphonylurea or a basal insulin, you may get low blood sugar

(hypoglycaemia). This may make it difficult to concentrate and you may feel dizzy or sleepy. If this happens do not drive or use any tools or machines.

Important information about some of the ingredients of Lyxumia

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially “sodium-free”.

This medicine contains metacresol which may cause allergic reactions.

3. How to use Lyxumia

Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

How much to inject

- The starting dose is 10 micrograms once a day for the first 14 days – injected using the **green** pen.
- The dose from then onwards will be 20 micrograms once a day -using the **purple** pen.

When to inject

Inject Lyxumia in the hour before your first meal of the day or in the hour before your evening meal.

Where to inject

Inject Lyxumia into the skin (subcutaneously) of your stomach area (abdomen), upper leg (thigh) or upper arm.

Learning how to use the pre-filled pens

Before you use the pen for the first time, your doctor or nurse will show how to inject Lyxumia.

- **Always read the “Instructions for Use” provided in the box.**
- **Always use the pen as described in the “Instructions for Use”.**

Other important information about using the pre-filled pens

There is more information on how to use the pens in the “Instructions for Use”. The most important points are:

- Always use a new needle for each injection. Throw the needles away after each use.
- Only use needles that are compatible for use with Lyxumia pen (see “Instructions for Use”).
- **You must activate your Lyxumia pen before you use it for the first time.** This is to make sure that it is working correctly and that the dose for your first injection is correct.
- If you think your Lyxumia pen may be damaged, do not use it. Get a new one. Do not try to repair the pen.

If you use more Lyxumia than you should

If you use more Lyxumia than you should, talk to your doctor immediately. Too much Lyxumia can make you feel sick or be sick.

If you forget to use Lyxumia

If you miss a dose of Lyxumia, you can inject it in the hour before your next meal. Do not take two doses at the same time to make up for a forgotten injection.

If you stop using Lyxumia

Do not stop using Lyxumia without talking with your doctor. If you stop using Lyxumia, your blood sugar levels can increase. If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some severe allergic reactions (such as anaphylaxis) have been reported uncommonly in patients receiving Lyxumia. You should seek immediate medical attention if you experience symptoms like swelling of the face, tongue or throat which causes difficulty with breathing.

The most frequent side effects reported with Lyxumia that may affect more than 1 in 10 users (frequency very common) were nausea (feeling sick) and vomiting. These side effects were mostly mild and usually go away over time.

Other very common side effects reported with Lyxumia

- Diarrhoea
- Headache
- Low blood sugar (hypoglycaemia “hypo”) especially when Lyxumia is used with insulin or a sulphonylurea

The warning signs of low blood sugar may include cold sweat, cool pale skin, headache, feeling drowsy, weak, dizzy, confused or irritable, feeling hungry, fast heart beat and feeling jittery. Your doctor will tell you what to do if you get a low blood sugar.

This is more likely to happen if you also take a sulphonylurea or a basal insulin. Your doctor may reduce your dose of these medicines before you start using Lyxumia.

Common side effects: may affect up to 1 in 10 users

- Flu (influenza)
- Cold (upper respiratory tract infection)
- Feeling dizzy
- Indigestion (dyspepsia)
- Back pain
- Cystitis
- Viral infection
- Low blood sugar (when Lyxumia is taken with metformin)
- Somnolence

Uncommon side effect: may affect up to 1 in 100 users

- Hives (urticaria)

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. How to store Lyxumia

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pen label and on the carton after EXP. The expiry date refers to the last day of the month.

Before first use

Store in a refrigerator (2°C-8°C). Do not freeze. Keep away from the freezer compartment.

During use of the pen

The pen can be used for 14 days when stored at a temperature below 30°C. Do not freeze. Do not store with attached needle. When you are not using the pen, the cap must be replaced on the pen to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lyxumia contains

- The active substance is lixisenatide.
- Each dose of Lyxumia 10 contains 10 micrograms of lixisenatide (50 micrograms per ml).
- Each dose of Lyxumia 20 contains 20 micrograms of lixisenatide (100 micrograms per ml).
- The other ingredients are glycerol 85 %, sodium acetate trihydrate, methionine, metacresol, hydrochloric acid (for pH adjustment), sodium hydroxide solution (for pH adjustment) and water for injections.

What Lyxumia looks like and contents of the pack

Lyxumia is a clear and colourless solution for injection (injection) filled in a glass cartridge inserted in a pre-filled pen.

Each green Lyxumia pen contains 3 ml of solution , delivering 14 doses of 10 micrograms for Lyxumia 10. Pack size of 1 pre-filled pen. Each purple Lyxumia pen contains 3 ml of solution , delivering 14 doses of 20 micrograms for Lyxumia 20. Pack sizes of 1, 2 or 6 pre-filled pens.

A treatment initiation pack is also available for use during the first 28 days of treatment. The treatment initiation pack contains one green pen for Lyxumia 10 micrograms and one purple pen for Lyxumia 20 micrograms. Not all pack sizes may be available in your country.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

sanofi-aventis groupe

54, rue La Boétie
F – 75008 Paris
France

Manufacturer:

Sanofi-Aventis Deutschland GmbH
Industriepark Höchst
65926 Frankfurt am Main
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This leaflet was last revised in February 2013.

THIS MEDICAMENT

Is a product, which affects your health, and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers,
Union of Arab Pharmacists.