Package leaflet:
Information for the user

Lyxumia® 10 micrograms
solution for injection

Lyxumia® 20 micrograms
solution for injection

lixisenatide

SANOFI

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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.

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- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lyxumia is and what it is used for

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.
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

Do not use Lyxumia:
- if you are allergic to lixisenatide or any of the other ingredients of this medicine (listed in section 6).

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 breakdown glucose because there is not enough insulin) since this medicine will not be right for you
- you have or have 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 any meal of the day. Preferably inject Lyxumia before the same meal every day, when you have chosen the most convenient meal for your injection.

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.

Stop taking Lyxumia and contact a doctor immediately if you notice any of the following serious side effects:
- Severe and persistent pain in the abdomen (stomach area) which might reach through to your back, as well as nausea and vomiting, as it could be a sign of an inflamed pancreas (pancreatitis).

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
- Injection site reactions (such as itching).

Uncommon side effect:
may affect up to 1 in 100 users
- Hives (urticaria)

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

United Kingdom
You can also report side effects directly via the Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard

Ireland
You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971;
Fax: +353 1 6762517.
Website: www.hpra.ie;
E-mail: medsafety@hpra.ie

Malta
ADR Reporting, The Medicines Authority, Post-Licensing Directorate, 203 Level 3, Rue D'Argens, GŻR-1368 Gżira

Website:
www.medicinesauthority.gov.mt
e-mail:
postlicensing.medicinesauthority@gov.mt

By reporting side effects, you can help provide more information on the safety of this medicine.

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.
Not all pack sizes may be available in your country.
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
Germany

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Detailed information on this medicine is available on the European Medicines Agency web site:
http://www.ema.europa.eu.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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