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 who are not enough to control your blood sugar levels. These may include:

- oral antidiabetics (such as metformin, sitagliptin, pioglitazone or sulphfonylureas) and/or
- a basal insulin, a type of insulin which works as a basal insulin, or
- an oral antidiabetic (such as metformin, or a sulphonylurea

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 diabetes or have had diabetes (diabetic retinopathy) or have had pancreas (pancreatitis) or
- you have a severe stomach or gut problem such as a disease of the muscles of the stomach called "gastroparesis" which results in delayed emptying of the stomach,
- you have severe kidney disease or are on dialysis as the use of this medicine will not be recommended,
- you have or have had inflammation of the pancreas (pancreatitis),
- you are taking other medicines that, 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 lyxisenatide),
- you experience loss of fluids/dehydration, e.g. in case of vomiting, diarrhea, nausea and diarrhoea. It is important to avoid dehydrating by drinking plenty of fluids, especially when starting treatment with lyxisenatide,
- 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 lyxisenatide

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines. They may change the dose 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 breastfeeding

Lyxumia should not be used during pregnancy. It is not known if Lyxumia may harm your unborn child. Lyxumia should not be used if breastfeeding. 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. You should read the "Instructions for Use" before you start using this medicine as the use of Lyxumia may not be recommended.

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 lyxisenatide 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 pens 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 one needle for each injection.
- You must dispose of the needle after each use, in an approved sharps container,
- Follow local recommendations. Speak to your doctor, nurse or pharmacist about how to dispose of sharps.
- 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

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 swelling of the face, tongue or throat which causes difficulty with breathing.

Stop taking lyxisenatide 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 the back, as well as nausea and vomiting. 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 side effects include:

- Very common side effects: may affect more than 1 in 10 people
- Common side effects: may affect up to 1 in 10 people
- Uncommon side effects: may affect up to 1 in 100 people
- Rare side effects: may affect up to 1 in 10 000 people
- Very rare side effects: may affect up to 1 in 100 000 people

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.

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 package carton after EAP. 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 a needle attached. When you are not using the pen, keep the cap on the pen in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of 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 lixisenatide.
- Lyxumia 10 micrograms solution for injection: Each dose contains 10 micrograms of lixisenatide (100 micrograms per ml).
- Lyxumia 20 micrograms solution for injection: Each dose contains 20 micrograms of lixisenatide (100 micrograms per ml).

- The other ingredients are glycerol 85 %, sodium acetate trihydrate, methylcellulose, 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 pen of Lyxumia 10 micrograms solution for injection contains 1 ml of solution, delivering 14 doses of 10 micrograms. Pack size of 1 pre-filled pen.

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

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

United Kingdom
Sanofi,
Tel: 0800 035 2525
Email: uk.medicalinformation@sanofio.com

Marketing Authorisation Holder and Manufacturer
Sanofi-Aventis Deutschland GmbH
Industriepark Höchst – 65926 Frankfurt am Main
Germany

Marketing Authorisation Holder
sano-friends group
54, rue La Boétie
F- 75008 Paris
France

For any information about this medicine, you can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellcard or search for Yellow Card in the Google Play or Apple App Store.

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

Pack size of 1 or 2 pre-filled pens.

There is no experience with Lyxumia in patients receiving Lyxumia. You should seek immediate medical attention if you experience swelling of the face, tongue or throat which causes difficulty with breathing.