

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. See section 4.

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

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 dose is 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. You must dispose of the needle after each use, in an appropriate sharp's container, following 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

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 side effects include

Very common side effects:
may affect more than 1 in 10 people

- 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 people

- 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)
- Drowsiness (somnolence)
- Injection site reactions (such as itching).

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

- Hives (urticaria)

Rare side effect:
may affect up to 1 in 1,000 people

- A delay in the emptying of the stomach

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. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA 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.

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

If your pen shows any signs of damage or does not seem to function properly, you should seek the advice of your pharmacist who will tell you what to do.

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 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 purple pen of Lyxumia 20 micrograms solution for injection contains 3 ml of solution, delivering 14 doses of 20 micrograms.

Pack sizes of 1, 2 or 6 pre-filled pens.

Manufacturer and product licence holder

Manufactured by Sanofi-Aventis Deutschland GmbH, Industriepark Höchst - 65926 Frankfurt am Main, Germany.

Procured from the EU by Product Licence holder:
Drugsrus Ltd, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD.
Repackaged by P.I.E. Pharma Ltd.

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For any information about this medicine, please contact the Product Licence Holder: Drugsrus Ltd, 5 Sandridge Close, Harrow, Middlesex HA1 1XD.

Email: regulatory@drugsrus.co.uk

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Is this leaflet hard to see or read?
Call 020 8423 2111 to obtain the
leaflet in a format suitable for you.**

Lyxumia® 20 micrograms solution for injection

(lixisenatide)

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INSTRUCTIONS FOR USE

Each pre-filled pen contains **14** doses, each dose contains **20 micrograms** in **0.2 ml**.

Section 1 – IMPORTANT INFORMATION

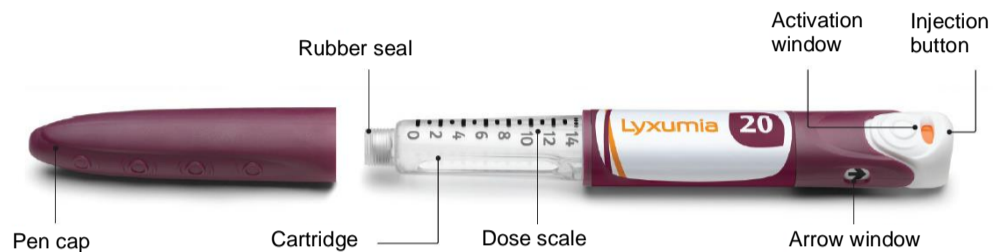
Read these instructions carefully before using your Lyxumia pen. Keep this leaflet for future reference.

Lyxumia pen Information

Lyxumia comes as a pre-filled pen for injection.

- **Only inject one dose per day.**
- Each Lyxumia pen contains 14 pre-set doses. There is no need to measure each dose.
- Talk with your doctor, pharmacist or nurse about how to inject correctly before using it.
- If you cannot follow all the instructions completely on your own, or are not able to handle the pen (for example, if you have vision problems), only use it if you have help.

About Your Lyxumia pen



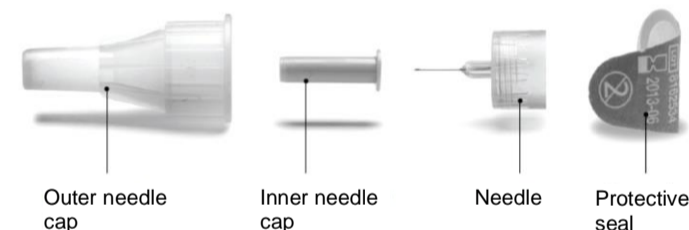
- This pen is only for one person. Do not share it with anyone else.
- Always check the label to ensure you have the correct Lyxumia pen. Also, check it has not passed the expiry date. Using the wrong medicine could be harmful to your health.
- Do not try to take liquid out of the cartridge using a syringe.



Black plunger

The plunger will move along the dose scale after each injection. In the example above, the dose number shows there are 13 injections left.

About your needle (supplied separately)



- Only use needles that are approved for use with Lyxumia. Use 29 to 32 gauge disposable pen needles with your Lyxumia pen. Ask your doctor, pharmacist or nurse which needle gauge and length is best for you.
- If another person is giving the injection, they should take care not to injure anyone accidentally with the needle. This could possibly pass on infection.
- Always use a new needle for each injection. This helps prevent contamination of Lyxumia or possible needle blockage.

Section 2 – GETTING STARTED

- Activate the pen on the same day as your first injection.

First activate your new pen

- **Before injecting a dose** – before injecting you must first remove excess liquid from your new pen. This is done once and is called the 'activation' process. Steps 1 to 5 below show you how to do this.
- Activation is done to make sure that the pen is working correctly and that the dose for your first injection is correct.
- **Do not repeat** the activation process or you will not obtain 14 doses from your Lyxumia pen.

The pictures below show how the activation window on the injection button of your pen changes after activation.

New pen
(orange window)



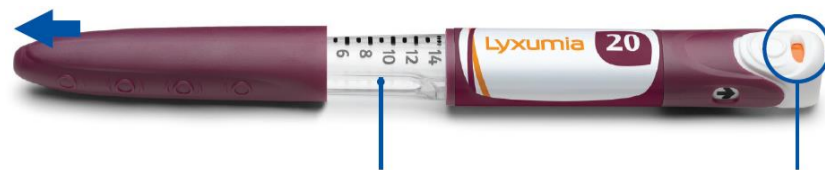
Pen ready for injections
(white window)

The pen is activated and ready for injections. The window remains white after activation.



How to activate your new Lyxumia pen

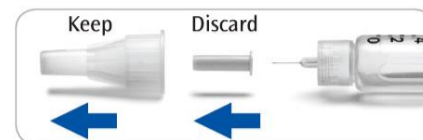
Step 1 Pull off the pen cap and check the pen



Check the liquid. It should be clear and colourless and with no particles. If not, do not use this pen. Contact your doctor, pharmacist or nurse.

Check that the activation window is orange.

Step 2 Attach a needle and remove the needle caps



Always use a **new** needle for activation. Remove the protective seal from the outer needle cap. Line up the needle with the pen. Keep it straight as you screw it on.

Take care not to injure yourself when the needle is exposed. Pull off the outer and inner needle caps. Keep the outer needle cap – you will need it to remove the needle later.

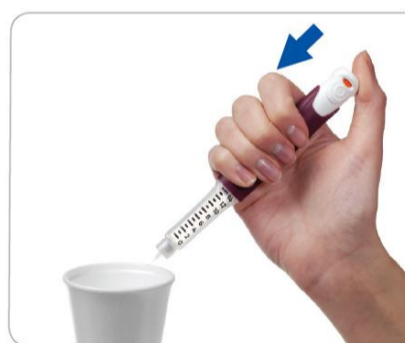
Step 3 Pull injection button out



Pull the injection button out firmly until it stops.

The arrow will now be pointing towards the needle.

Step 4 Press and hold the injection button to remove excess liquid



Point the needle into a suitable container (like a paper cup or tissue) to capture the liquid so that it can be thrown away.

Press the injection button all the way in. You may feel or hear a "click".

Keep the injection button pressed in and slowly count to 5 in order to expel the last drops.

If no liquid comes out see the "Questions and answers" section. Check that the activation window is now white.

Step 5 The pen is now activated. Do not activate this pen again. For your first injection go directly to Section 3 - Step C.

You **do not** need to replace the needle between activation and your first injection.

Section 3 – DAILY USE OF PEN

Only follow this section when the activation window is **white**. Inject only **one** dose each day.

Step A Pull off the pen cap and check the pen



Check the liquid. It should be clear and colourless with no particles. If not, do not use this pen.

In case of air bubbles see the "Questions and answers" section.

Check the number of doses in the pen. This is shown by the placement of the black plunger in the dose scale.

Check that the activation window is white. If it is orange, go to Section 2.

Check the label on your pen to make sure you have the correct medicine.

Table of activation and disposal

In the table, write the date when you activated your pen and the date to throw it away 14 days later.

Pen	Date of activation	Date to discard
1		
2		
3		
4		
5		
6		

Storage

General information

- Keep your Lyxumia pens in a safe place out of the reach and sight of children.
- Protect your Lyxumia pens from dust and dirt.
- Replace the pen cap after each use in order to protect from light.
- Do not use Lyxumia after the expiry date which is stated on the label and on the carton. The expiry date refers to the last day of that month.

Before activation of the pen:

- Store your unused Lyxumia pens in the refrigerator, 2°C to 8°C.
- Do not freeze Lyxumia pens and do not use Lyxumia if it has been frozen.
- Allow your pen to warm at room temperature before using.

After activation of the pen:

- Once activated, store your Lyxumia pen below 30°C. Do not freeze Lyxumia once it has been activated.
- Do not store your Lyxumia pen with the needle attached. An attached needle might lead to contamination and possible intake of air which might impact the dose accuracy.
- Once your Lyxumia pen is activated it can be used for up to 14 days. Throw away a used Lyxumia pen after 14 days. Do this even if there is some medicine left in the pen.

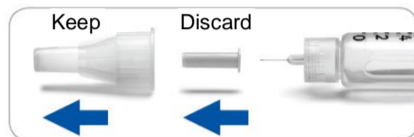
Step B Attach a new needle and remove the needle caps



Always use a **new needle** for each injection.

Remove the protective seal from the outer needle cap.

Line up the needle with the pen. Keep it straight as you screw it on.



Take care not to injure yourself when the needle is exposed.

Pull off the outer and inner needle caps. Keep the outer needle cap – you will need it to remove the needle later.

Disposal

- Replace the pen cap before you throw away your Lyxumia pen.
- Throw away your Lyxumia pen, ask your pharmacist how to throw away medicines you no longer use.

Step C Pull the injection button



Pull the injection button out firmly until it stops.



The arrow will now be pointing towards the needle.

Maintenance

- Handle your Lyxumia pen with care.
- You can clean the outside of your Lyxumia pen by wiping it with a damp cloth.
- Do not soak, wash or put liquid on (lubricate) your Lyxumia pen, this may damage it.
- If you think your Lyxumia pen may be damaged, do not use it. Do not try to repair the pen.

Step D Press and hold the injection button to inject the dose



Grasp a fold of skin and insert the needle (see the "Injection sites" section about where to inject).

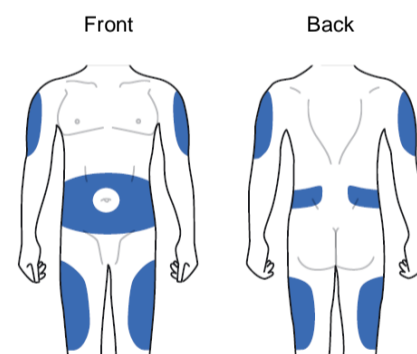
Press the injection button all the way in. You may feel or hear a "click".

Keep the injection button pressed in and slowly count to 5 to get the full dose.



Your dose has now been given. Pull the needle out of your skin.

Injection sites



Lyxumia must be injected under the skin and can be injected in any of the areas shown above in blue. These are the thigh, abdomen or upper arm. Ask your doctor, pharmacist or nurse about how to inject correctly.

Step E Remove and throw away needle after each injection



Put the outer needle cap on a flat surface. Guide the needle into the outer needle cap.

Put the outer needle cap back on.



Squeeze the outer needle cap to grip the needle and use it to unscrew the needle from the pen.



Ask your pharmacist how to throw away the needle you no longer use. Replace the pen cap.

Step F

Repeat all steps in Section 3 for each injection. Throw away a pen **14 days after activation**. Do this even if there is some medicine left in the pen.

Questions and answers

What if I forget to activate the Lyxumia pen or inject myself before activation?

If you have injected yourself before activating the pen, do not correct this by giving yourself a second injection. Contact your doctor, pharmacist or nurse for advice on checking your blood sugar.

What if there are air bubbles in the container?

Small air bubbles in the container are normal - they will not harm you. Your dose will be correct and you can keep following the instructions. Contact your doctor, pharmacist or nurse if you need help.

What if no liquid comes out during activation?

The needle may be blocked or not properly screwed on. Remove the needle from the pen, attach a new one and repeat Steps 4 and 5 only. If still no liquid comes out, your Lyxumia pen may be damaged. Do not use this Lyxumia pack. Contact your doctor, pharmacist or nurse for help.

What if it is hard to press the injection button all the way in?

The needle may be blocked or not properly screwed on. Pull the needle out of your skin and remove the needle from the pen. Attach a new needle and repeat Steps D and E only. If it is still hard to press the injection button, your Lyxumia pen may be damaged. Do not use this Lyxumia pack. Contact your doctor, pharmacist or nurse for help.

If you have any questions about Lyxumia or about diabetes, ask your doctor, pharmacist or nurse or call the local Sanofi number in the Lyxumia "Package leaflet: Information for the user" (provided separately in the box).