LYXUMIA®
lixisenatide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Lyxumia. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Lyxumia against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Lyxumia Is Used For

Lyxumia contains the active substance lixisenatide.

Lyxumia is a medicine used to control the blood sugar level when it is too high in adult patients with type 2 diabetes mellitus.

Lyxumia is used with other antidiabetic medicines for diabetes when they are not enough to control your blood sugar levels. Your doctor will prescribe the best combination to manage your type 2 diabetes mellitus.

It is also important to control your diet and exercise while using Lyxumia.

Check with your doctor or healthcare professional if you are not sure whether your antidiabetic medicines contain a sulfonylurea or basal insulin.

Diabetes mellitus is a condition in which your pancreas does not produce enough insulin to control your blood sugar (glucose) level. Lyxumia helps to control your blood sugar levels only when it is too high.

Lyxumia is not a substitute for insulin in patients who require insulin treatments for their diabetes. In some cases it may be used as well as insulin.

Your doctor, however, may have prescribed Lyxumia for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

This medicine is only available with a doctor's prescription.

Before You Use Lyxumia

When you must not use it

Do not use Lyxumia if:

- you have type 1 diabetes or diabetic ketoacidosis (often caused by very high blood glucose levels).
- you are allergic to lixisenatide or meta-cresol or any of the ingredients listed at the end of this leaflet.

You must not become pregnant while using Lyxumia.

It is not known if Lyxumia increases the risk of birth defects in humans.

Do not use it if you are breastfeeding.

Lyxumia may pass into breast milk and therefore there is a possibility that the breastfed baby may be affected.

Do not give Lyxumia to a child or adolescent.

Lyxumia has not been studied for use in children or adolescents under 18 years old.

Do not use it after the expiry date (EXP) printed on the pack.

If you use it after the expiry date has passed, it may not work as well.

Do not use it if the packaging is torn or shows signs of tampering or if the pen appears damaged. Return the product to your pharmacist if it has expired or is damaged.

Do not use Lyxumia if you see solid particles or if the solution is cloudy or coloured.

Talk to your doctor if you are not sure if you should start using Lyxumia.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are also taking a sulfonylurea (such as glimepiride or glibenclamide).

Your doctor may tell you to test your blood sugar levels. This will help your doctor to decide if the dose of the sulfonylurea needs to be changed.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- pancreatitis
- a history of persistent, severe abdominal pain.

Tell your doctor if you have severe problems with your stomach or food digestion.

Lyxumia slows stomach emptying so food passes more slowly through your stomach.
Tell your doctor if you are pregnant or plan to become pregnant.

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

Tell your doctor if you are breastfeeding or planning to breastfeed.

Lyxumia may pass into breast milk and therefore there is a possibility that this may affect your baby.

If you have not told your doctor about any of the above, tell them before you use Lyxumia.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor or pharmacist if you are taking a sulfonylurea (such as glimepiride or glibenclamide).

This is because using Lyxumia at the same time may cause your blood sugar level to become too low (hypoglycaemia or a “hypo”).

When you first start using these medicines together, your doctor may tell you to lower the dose of the sulfonylurea.

If you are not sure if the medicines you are taking contain a sulfonylurea, ask your doctor, diabetes educator/nurse or pharmacist.

If you are taking a sulfonylurea as well as Lyxumia your doctor may ask you to test your blood sugar levels to begin with. This will help your doctor to decide if the dose of the sulfonylurea needs to be changed.

Some medicines may be affected by Lyxumia or may affect how it works. You may need different amounts of your medicines or you may need to take your medicines at different times.

This includes:

- Medicines that need to pass through the stomach quickly such as antibiotics or stomach resistant tablets or capsules. Lyxumia slows stomach emptying and can affect these medicines
- Some medicines may need to be taken an hour before or 11 hours after your Lyxumia dose.

Your doctor and pharmacist have more information on how to manage your other medicines while using Lyxumia.

How To Use Lyxumia

How much to use

Carefully follow all the directions given to you by your doctor or health care professional.

They may differ from the information contained in this leaflet.

- 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.

Make sure you are using the correct injection pen. Always check the label on the pen before each injection to make sure you are using the right medicine.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to use.

Follow the instructions they give you.

These directions may differ from the information contained in this leaflet. If you take the wrong dose, Lyxumia may not work as well or you may experience side effects. Too much or too little Lyxumia can cause serious effects.

It is very important that you manage your diabetes carefully.

How to use it

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

Your doctor will tell you how much Lyxumia you will need to use each day.

Read carefully the "Lyxumia pen Instructions for Use" provided in the carton. You must use the pen as described in these Instructions for Use.

You must activate your LXYUMIA Pen before you use it for the first time.

This will make sure that it is working correctly and that the dose for your first injection is correct. Carefully follow the instructions provided with your Lyxumia pen for attaching a needle.

Always use a new needle for each injection. Carefully dispose of the needles after each use.

Your Lyxumia pen is pre-filled and ready to use. Once all the medicine is used you cannot replace the cartridge. You will need to use a new pen.

Injecting a dose

Do not use Lyxumia if it is not clear and colourless or if it contains particles. Lyxumia should be injected under the skin (subcutaneously) of your
stomach area (abdomen), upper leg (thigh) or the back of your upper arm. Be careful not to inject it into a muscle or vein. To reduce the chance of local skin reaction, change the injection site within each particular area you are using so that the same site is not used more often than once a month.

Read the “instructions for use leaflet” before beginning Lyxumia therapy.

Read the instruction leaflet each time you get a new pen in case something has changed.

Refer to the instruction leaflet each time you use this medicine.

After injecting

Using the outer needle cap, unscrew the needle and dispose of it safely into a sharps container.

Do not share needles or injection devices. Do not reuse needles.

Do not attempt to replace the cartridge in your Lyxumia pen.

The cartridge in your Lyxumia pen cannot be removed or replaced. Empty pens must not be reused and must be properly discarded.

Ask your pharmacist how to discard the pen.

When to use it

Lyxumia should be injected once a day.

Lyxumia should be injected within the hour before a meal (either breakfast, lunch or dinner). It is preferable to use Lyxumia before the same meal every day, when the most convenient meal has been chosen.

If you are not sure when to use it, ask your doctor or pharmacist.

How long to use it

Continue using your medicine for as long as your doctor or pharmacist tells you.

The medicine helps control your condition, but it does not cure it. Therefore, you must use it every day.

Ask your doctor or pharmacist if you are not sure how long to use the medicine for.

If you miss a dose

Lyxumia should be used at approximately the same time each day. If you miss taking your dose at the regular scheduled time, your blood sugar levels may become high (hyperglycaemia).

If you miss a dose of Lyxumia, you can inject the dose within the hour before your next meal.

If you have missed a dose and are not sure what you should do, contact your doctor or healthcare professional for specific advice.

Do NOT use a second dose of Lyxumia on the same day to make up for a dose you’ve missed.

The risk of hyperglycaemia is increased if you:

• miss doses of Lyxumia
• have uncontrolled diabetes
• exercise less than usual
• eat more carbohydrates than usual
• are ill or stressed

High blood sugar levels over a period of time can lead to too much acid in the blood (diabetic ketoacidosis).

If you are not sure what to do, ask your doctor or pharmacist.

If you use too much (overdose)

Your Lyxumia pen delivers a set dose of your medicine. If you accidentally inject a second dose on the same day, you may feel sick or be sick.

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have used too much Lyxumia.

Do this even if there are no signs of discomfort or poisoning.

While You Are Using Lyxumia

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are using Lyxumia.

Make sure all friends, relatives, workmates or carers know that you have diabetes.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using Lyxumia.

If you plan to travel overseas ask your doctor, diabetes educator/nurse for a letter explaining why you are taking injectable devices with you. You may not be able to get Lyxumia in the country that you are visiting.

If you become pregnant while you are taking this medicine, stop taking it and tell your doctor or pharmacist immediately.
Things you must not do
Do not use Lyxumia more often than recommended by your doctor.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not stop using Lyxumia without checking with your doctor.

If you stop using Lyxumia, your blood sugar levels can increase.

Do not give this medicine to anyone else, even if they have the same condition as you.

Things to be careful of
Tell your doctor if you drink alcohol.

Alcohol may mask the symptoms of low blood sugar levels (hypoglycaemia) or make it worse.

Be careful driving or operating machinery.

If you use Lyxumia with a sulphonylurea or with a combination of a sulfonylurea and a basal insulin, you may get low blood sugar (hypoglycaemia). This may cause dizziness or reduce your ability to concentrate.

Side Effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Lyxumia.

Lyxumia helps most people with type 2 diabetes to reduce their blood glucose levels, but it may have unwanted side effects in a few people.

When Lyxumia is used with a sulphonylurea or with a combination of a sulfonylurea and a basal insulin, your risk of low blood sugar levels (hypoglycaemia) can increase.

Your doctor may reduce the dose of these medicines if this happens.

The first symptoms of mild to moderate hypoglycaemia can come on suddenly. They may include:

- cold sweat, cool pale skin
- fatigue, drowsiness, unusual tiredness and weakness
- nervousness, anxious feeling
- tremor, rapid heart beat
- confusion, difficulty concentrating
- excessive hunger
- vision changes
- headache, nausea

If you are experiencing any of these symptoms of hypoglycaemia, immediately eat some sugary food or have a drink, e.g. lollies, biscuits or fruit juice.

If your symptoms continue go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- hives or itchy pinkish swellings on the skin
- feeling faint
- passing of little or no urine
- drowsiness
- any severe skin reaction
- severe abdominal pain which may also be accompanied by diarrhoea and/or nausea and/or vomiting

These are very serious side effects. If you have them, you may have had a serious reaction to Lyxumia. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.
After Using Lyxumia

Storage

Keep your Lyxumia pen in the carton until it is time to use it.
Keep the cap on your Lyxumia pen until you need to use it.
The ingredients in Lyxumia may not work as well if exposed to light for long periods.

Before first Use

Lyxumia must be stored refrigerated between 2°C and 8°C in the outer packaging in order to protect it from light. Keep it away from the freezer compartment.

During use of the pen

The pen can be used for 14 days. Lyxumia can be kept out of the refrigerator at a temperature not exceeding 30°C. Do not refrigerate or freeze it after first use. The pen cap should be replaced on the pen after each use to protect it from light. The pen should not be stored with a needle attached.
Do not use if frozen.

Keep the medicine in a cool dry place where the temperature stays below 30°C.
Do not store it or any other medicine in the bathroom or near a sink.
Do not leave it in the car on hot days or on window sills.
Heat and dampness and light can destroy some medicines.
Keep it where children cannot reach it.

Disposal

If your doctor or pharmacist tells you to stop using Lyxumia or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Product Description

What it looks like

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

Lyxumia is available as 2 different pens which deliver either a 10 microgram or 20 micrograms dose.

Each green coloured Lyxumia pen contains 3 ml of solution, delivering 14 doses of 10 micrograms for Lyxumia 10 mcg.

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

Lyxumia is available in packs containing 1 pen for Lyxumia 10 micrograms and in packs containing 1, 2 or 6 pens for Lyxumia 20 micrograms.

For treatment initiation, Lyxumia is available in a pack containing one pen for Lyxumia 10 micrograms and one pen for Lyxumia 20 micrograms.

Not all pack sizes may be marketed.

Ingredients

Active Ingredient:
Each 0.2 mL dose contains either 10 micrograms or 20 micrograms of the active ingredient, lixisenatide

Inactive Ingredients:
glycerol (85%) sodium acetate methionine meta-cresol hydrochloric acid sodium hydroxide water for injections

Lyxumia does not contain sucrose, gluten, tartrazine or any other azo dyes.

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Lyxumia contains less than 1 mmol sodium (23mg) per dose i.e essentially “sodium free”

Manufacturer/Sponsor

Lyxumia is supplied in Australia by:
sanofi-aventis australia pty ltd 12-24 Talavera Road Macquarie Park NSW 2113

Lyxumia is currently not marketed in New Zealand

Australian Registration Number(s):
Lyxumia 10 microgram – AUST R 192722
Lyxumia 20 microgram – Aust R 192719
Lyxumia Treatment Initiation Pack - Aust R 192721

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