**What is in this leaflet**

lixisenatide

Lyxumia® 10 micrograms

Package leaflet:

Lyxumia is used with other medicines for it is too high. It is used in adults with type 2 body to control your blood sugar level when it is too high. It is used to help your

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.

**Warnings and precautions**

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

- you have type 1 diabetes or diabetic ketoadiposis (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 or gut (paralytic ileus) 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 biguanide
- 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 lyxisenatide)
- 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 any stomach problems which can cause shortness of breath or ankle swelling, since there is limited experience in this patient group.

**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. The effect of some medicines you might swallow may be affected by Lyxumia.

Some 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) may affect up to 1 in 10 people

**Pregnancy and breast-feeding**

Lyxumia should not be used if breast-feeding. 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 if you are 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 machines.

**Important information about some of the ingredients of lyxisenatide**

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium-free". This medicine contains metazachlor which may cause allergic reactions.

**4. Possible side effects**

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 injection is 10 micrograms once a day for the first 14 days – injecting 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 left (high) 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 in lyxisenatide pens in the “Instructions for Use”.
- You may be pregnant or are planning to have a baby. Ask your doctor, pharmacist or nurse before taking this medicine.

**If you stop using lyxisenatide**

Do not stop using lyxisenatide without talking with your doctor. If you stop using lyxisenatide, 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 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.

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

**6. Contents of the pack and other information**

**What Lyxumia contains**

- The active substance is lixisenatide.
- Lyxumia may affect blood sugar levels when used for injection.
- Each dose contains 10 micrograms of lixisenatide (50 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, methionine, metacresol, hydrochloric acid (for pH adjustment), sodium hydroxide solution (for pH adjustment) and water for injection.

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 contains 0.6 ml solution, delivering 12 doses of 10 micrograms.

Each pack of Lyxumia 20 micrograms solution contains 1 ml solution, delivering 24 doses of 20 micrograms.

**How to use Lyxumia**

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**Do not use Lyxumia**

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

**What to do 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 have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.**