1. What Lyxumia is and what it is used for

Lyxumia is a prescription medicine. It is a solution for injection. Lyxumia is used in adults with type 2 diabetes or patients with type 1 diabetes to help control your blood sugar levels. Lyxumia is also used in children with type 1 diabetes.

2. How to use Lyxumia

This medicine is prescribed by your doctor. The treatment initiation pack contains Lyxumia and one purple pen of solution for injection. After the pen is filled with Lyxumia solution, the treatment initiation pack is discarded. Do not reuse to fill the pen again.

3. How to use Lyxumia

Always use this medicine exactly as your doctor has told you. The correct dose of the active ingredient lixisenatide should be injected in the hour before your next meal. Do not try to repair the pen.

If you want 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 of Lyxumia at the same time to make up for a forgotten injection.

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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some possible side effects (such as annoyances) 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.

5. How to store Lyxumia

Do not use Lyxumia if:

- you have a severe stomach or gut problem
- 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 "gastraparesis" which results in delayed stomach emptying
- you have severe kidney disease or you are dialyzed as your dialysis is stated on this medicine will not be recommended
- you are also taking a sulphonylurea as a basal insulin. This is because low blood sugar (hypoglycaemia) can occur. Your doctor may want to control your blood sugar levels and then decide to reduce your dose of basal insulin.
- 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.

In these people, the most frequent side effects reported with Lyxumia that may affect more than 1 in 10 people (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:

• Uncommon side effects:
  - Hives (urticaria)
  - Proteinuria
  - Cystitis
  - Indigestion (dyspepsia)

• Very common side effects:
  - Low blood sugar (hypoglycaemia ("hypo") especially when lyxumia is used with insulin or 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 thirsty. Your doctor will tell you what to do if you get a low blood sugar.

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