Package leaflet: Information for the user

Lyumjev® 100 units/ml solution for injection in cartridge
insulin lispro

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, nurse or pharmacist.
- 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lyumjev is and what it is used for
2. What you need to know before you use Lyumjev
3. How to use Lyumjev
4. Possible side effects
5. How to store Lyumjev
6. Contents of the pack and other information

1. What Lyumjev is and what it is used for

Lyumjev 100 units/ml solution for injection in a cartridge contains the active ingredient insulin lispro. Lyumjev is used to treat diabetes mellitus in adults, adolescents and children aged 1 year and above. It is a mealtime insulin that works more quickly than other medicines containing insulin lispro. Lyumjev contains ingredients that speed up absorption of insulin lispro into the body.

Diabetes is a condition in which your body does not make enough insulin or does not use insulin effectively, which results in effects such as high levels of sugar in the blood. Lyumjev is an insulin medicine that is used in the treatment of diabetes and so controls blood sugar. Effective treatment of diabetes, with good control of blood sugar, prevents long-term complications from your diabetes.

Treatment with Lyumjev helps to control blood sugar in the long term and prevent complications from your diabetes. Lyumjev has its maximum effect 1 to 3 hours after injection and the effect lasts for up to 5 hours. You should use Lyumjev at the start of the meal, or up to 20 minutes after starting the meal.

Your doctor may tell you to use Lyumjev as well as a longer- or intermediate-acting insulin. Do not change your insulin unless your doctor tells you to.

2. What you need to know before you use Lyumjev

Do NOT use Lyumjev
- if you think your blood sugar is dropping (**hypoglycaemia**). Further on, this leaflet tells you how to deal with low blood sugar (see section 3 under “If you use more Lyumjev than you should”).
- if you are **allergic** to insulin lispro 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 Lyumjev.

If you cannot see very well you will need help from someone who has been trained to give injections.

- **Low blood sugar** (hypoglycaemia).

Low blood sugar can be serious and untreated hypoglycaemia may even lead to death.
Lyumjev starts to lower blood sugar faster than some other mealtime insulins. If hypoglycaemia occurs, you may experience it earlier after an injection of Lyumjev. If you often have hypoglycaemia or have difficulty recognising it, please discuss this with your doctor or nurse. If your blood sugar levels are well controlled by your current insulin therapy or after long duration of diabetes, you may not feel the warning symptoms when your blood sugar is falling too low. Warning signs are listed later in this leaflet. For symptoms please see "Common problems of diabetes".

You must think carefully about when to have your meals, how often to exercise and how much to do. You must also keep a close watch on your blood sugar levels by testing your blood sugar often. Making changes to the types of insulin you use may cause your blood sugar to rise or fall too much. It may be necessary to increase the frequency of blood sugar testing if you are at risk of low blood sugars. Your doctor may need to change the doses of your other diabetes medicines.

- **High blood sugar** (hyperglycaemia).

Stopping or not taking enough insulin may lead to high blood sugar (hyperglycaemia) and diabetic ketoacidosis, serious conditions that can even lead to death. For symptoms please see "Common problems of diabetes".

- If your insulin treatment is being combined with one of a class of diabetes medicines called thiazolidinediones or glitazones, such as pioglitazone, tell your doctor as soon as possible if you get signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling caused by fluid retention (oedema).
- If you have a serious allergic reaction to insulin or any of the ingredients in Lyumjev, stop using this medicine and contact emergency medical services straight away.
- Always check the pack and the label for the name and type of the insulin when you get it from your pharmacy. Make sure you get the Lyumjev that your doctor has told you to use.
- Keep the carton, or keep a note of the batch number on the carton. If you have a side effect you can then provide that number when you report the side effect, see "reporting of side effects".
- Always use a new needle for each injection to prevent infections and blocked needles. If a needle is blocked replace it with a new needle.

- **Skin changes at the injection site.**

The injection site should be rotated to prevent skin changes such as lumps under the skin. The insulin may not work well if you inject into a lumpy area (see "How to use Lyumjev"). Contact your doctor if you are currently injecting into a lumpy area before you start injecting into a different area. Your doctor may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

Children and adolescents
This medicine is not recommended for use in children below the age of 1 year.

Other medicines and Lyumjev
Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines affect your blood sugar level - this may mean your insulin dose has to change.

Your blood sugar levels may fall (hypoglycaemia) if you take:

- other medicines for diabetes (oral and injectable)
- sulphonamide antibiotics (for infections)
- acetylsalicylic acid (for pain and mild fever and to prevent blood clotting)

- some antidepressants (monoamine oxidase inhibitors or selective serotonin reuptake inhibitors)
- some angiotensin converting enzyme (ACE) inhibitors (for example captopril, enalapril) (for some heart problems or high blood pressure)
- angiotensin II receptor blockers (for high blood pressure or heart problems)
- somatostatin analogues (such as octreotide, which are used to treat a rare condition involving too much growth hormone)

Your blood sugar levels may rise (hyperglycaemia) if you take:

- danazol (for endometriosis)
- the contraceptive pill (birth control pills)
- thyroid hormone replacement therapy (for thyroid problems)
- human growth hormone (for growth hormone deficiency)
- diuretics (for high blood pressure or if you have a build-up of water in your body)
- sympathomimetic agents (for serious allergic reactions or used in some cold remedies)
- corticosteroids (to treat asthma or autoimmune conditions)

Beta-blockers (used for high blood pressure, arrhythmia or angina) make it harder to recognise the warning signs of low blood sugar.

Lyumjev with alcohol
Your blood sugar levels may either rise or fall if you drink alcohol. Therefore the amount of insulin needed may change. You should therefore monitor your blood sugar level more often than usual.

Pregnancy and breast-feeding
If you are planning to have a baby, think you may be pregnant, are pregnant or breast-feeding, ask your doctor, nurse or pharmacist for advice before taking this medicine. The amount of insulin you need usually falls during the first 3 months of pregnancy and increases for the remaining 6 months. After you have had your baby your insulin requirements will likely return to how much you needed before your pregnancy.

There are no restrictions on treatment with Lyumjev during breast-feeding. If you are breast-feeding, you may need to alter your insulin intake or diet.

Driving and using machines
Your ability to concentrate and react may be reduced if you have hypoglycaemia. Please keep this possible problem in mind in all situations where you might put yourself and others at risk (e.g. driving a car or using machines). You should contact your doctor about driving if you have:
- frequent episodes of hypoglycaemia
- reduced or absent warning signs of hypoglycaemia

Lyumjev contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to use Lyumjev

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with them if you are not sure.

They will have told you exactly how much Lyumjev to use, when to use it, and how often. They will also tell you how often to visit your diabetes clinic.

To prevent the possible transmission of disease, each cartridge must be used by you only, even if the needle on the pen is changed.

You should always have spare insulin and another injection device in case you need them.

If you are blind or visually impaired you will need help from someone to make your injections.

Your doctor may tell you to use Lyumjev as well as a longer- or intermediate-acting insulin. Inject them separately. Lyumjev should not be mixed with any other insulin.

When to inject Lyumjev
Lyumjev is a mealtime insulin. You should use Lyumjev when you start to eat, or a minute or two before the meal; you also have the option to inject up to 20 minutes after starting the meal.

How much insulin to use
Your doctor will work out your dose based on your blood sugar and body weight and explain:
- How much Lyumjev you need at each meal.
- How and when to check your blood sugar level.
- How to change your insulin dose depending on your blood sugar levels.
- What to do if you change your diet, or change how much you exercise, if you are ill or if you are using other medicines.
- If you change the type of insulin you use, you may have to take more or less than before. This might just be for the first injection or it may be a gradual change over several weeks or months.

Do not use Lyumjev
- If it does not look like water. Lyumjev must be clear, have no colour and no solid pieces in it. Check each time you inject yourself.
- If Lyumjev has not been stored correctly (see section 5 "How to store Lyumjev").
- If the cartridge is damaged in any way, do not use.

Getting the pen ready to use
- First wash your hands. Disinfect the rubber membrane of the cartridge.
- **You must only use Lyumjev cartridges in Lilly insulin pens. Please make sure that Lyumjev or Lilly cartridges are mentioned in the leaflet accompanying your pen. The 3 ml cartridge only fits the 3 ml pen.**
- Follow the instructions that come with the pen. Put the cartridge into the pen.
- Use a new needle. (Needles are not included).
- Prime every time. The pen must be primed until you see insulin at the needle tip before each injection to make sure the pen is ready to dose. If you do not prime, you may get the wrong dose.

Injecting Lyumjev
- Before you make an injection, clean your skin.
- Inject under the skin (subcutaneous injection), as you were taught by your physician or nurse.
- After your injection, leave the needle in the skin for 5 seconds to make sure you receive the full dose. Make sure you inject at least 1 cm from the last injection and that you 'rotate' the places you inject (upper arm, thigh, buttocks or abdomen).
- If you do not have enough insulin in the pen to complete your dose, make a note of how much you still need to take. Prime a new pen and inject the remaining dose.
- If you need to inject another insulin at the same time as Lyumjev, use a different injection site.
- Do not inject directly into a vein.

After injecting
- As soon as you have done the injection, take the needle off the pen using the outer needle cap. This will keep the Lyumjev sterile and prevent leaking. It will also stop air going back into the

pen and the needle clogging up. **Do not share your needles. Do not share your pen.** Replace the cap on your pen. Leave the cartridge in the pen.
- If you are unsure how much you have injected then check your blood sugar levels before deciding if you need another injection.

Further injections
- Every time you plan to make an injection use a new needle. Before every injection, prime the pen to clear any large air bubbles.
- Once the cartridge is empty, do not use it again.

If you use more Lyumjev than you should
If you inject too much Lyumjev, or are unsure how much you have injected, a low blood sugar may occur. Check your blood sugar.

If your blood sugar is low (hypoglycaemia) and you can treat yourself, eat glucose tablets, sugar or drink a sugary drink. Then eat fruit, biscuits, or a sandwich, as your doctor or nurse has advised you and have some rest. This will often get you over a low blood sugar or a minor insulin overdose. Check your blood sugar again after 15-20 mins until blood sugar is stabilised.

If you are unable to treat yourself (severe hypoglycaemia) because you feel too dizzy, weak, confused, have difficulty talking, lose consciousness or have a seizure you may need to be treated with glucagon. This can be given by someone who knows how to use it. Eat glucose or sugar after the glucagon. If glucagon does not work, you will have to go to hospital or call emergency services. Ask your doctor to tell you about glucagon.

Tell everyone you spend time with that you have diabetes. Tell them what could happen if your blood sugar gets too low, including the risk of passing out.
Let them know that if you pass out, they must: turn you on your side to avoid choking, get medical help straight away and not give you any food or drink because you may choke.

If you forget to use Lyumjev
If you forget to use your insulin or you use less than you should, or are unsure how much you have injected, your blood sugar may get too high (hyperglycaemia). Check your blood sugar level to decide if an insulin dose is needed. Resume your usual dosing schedule at your next meal.

If you stop using Lyumjev
Do not stop or change your insulin unless your doctor tells you to. If you use less Lyumjev than you should, a high blood sugar may occur.

If high blood sugar (hyperglycaemia) is not treated it can be very serious and cause headaches, nausea, vomiting, abdominal pain, dehydration, unconsciousness, coma or even death (see section 4).

Three simple steps to reduce your risk of hypoglycaemia or hyperglycaemia are:
- Always keep a spare pen and cartridges, in case you lose your pen or cartridges or they get damaged.
- Always carry something to show you are diabetic.
- Always carry sugar with you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Low blood sugar (hypoglycaemia) is very common with insulin treatment (may affect more than 1 in 10 people). It can be very serious. If your blood sugar level falls too much you may become unconscious. Serious hypoglycaemia may cause brain damage and may be life-threatening. If you have symptoms of low blood sugar, act **immediately** to increase your blood sugar level. See section 3 under 'If you use more Lyumjev than you should'.

Allergic reactions are common (may affect up to 1 in 10 people). They may be severe and they may include the following symptoms:

- rash and itching over the whole body
- difficulty in breathing
- wheezing
- blood pressure dropping
- heart beating fast
- sweating

If you have a serious allergic reaction (including an anaphylactic attack) to insulin or any of the ingredients in Lyumjev, stop using this medicine and contact emergency medical service straight away.

Other side effects include

Common (may affect up to 1 in 10 people)
Injection site reactions. Some people get redness, pain, swelling or itching around the area of the insulin injection. This usually clears up in a few minutes to a few weeks without needing to stop Lyumjev. If you have injection site reactions, tell your doctor.

Uncommon (may affect up to 1 in 100 people)
Skin changes at the injection site: If you inject insulin too often at the same place, the fatty tissue may either shrink (lipoatrophy) or thicken (lipohypertrophy). Lumps under the skin may also be caused by the build-up of a protein called amyloid (cutaneous amyloidosis). The insulin may not work very well if you inject into a lumpy area. Change the injection site with each injection to help prevent these skin changes.

Other potential side effects
Swelling in arms or ankles due to fluid retention (oedema) particularly at the start of insulin therapy or during a change in your diabetes medicines.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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.

Common problems of diabetes

Low blood sugar
Low blood sugar (hypoglycaemia) means there is not enough sugar in the blood. This can be caused if:
- you take too much Lyumjev or other insulin;
- you miss or delay meals or change your diet;
- you exercise or work too hard just before or after a meal;
- you have an infection or illness (especially diarrhoea or vomiting);
- there is a change in your need for insulin for example if you lose weight; or you have trouble with your kidneys or liver which gets worse.

See section "If you use more Lyumjev than you should".

The first symptoms of low blood sugar usually come on quickly and include the following:

- tiredness
- rapid heart beat
- nervousness or shakiness
- feeling sick
- headache
- cold sweat

If you are not confident about recognising your warning symptoms, avoid situations such as driving a car, in which you or others would be put at risk by hypoglycaemia.

High blood sugar (hyperglycaemia) and diabetic ketoacidosis
Hyperglycaemia (too much sugar in the blood) means that the levels of glucose in your body are too high. Hyperglycaemia can be brought about by:
- not taking your insulin;
- using less insulin than your body needs;
- an imbalance between the amount of carbohydrates you eat and the insulin you take; or
- fever, infection or emotional stress.

The early symptoms of hyperglycaemia are:
- being very thirsty
- headache
- feeling sleepy
- urinating more often

Hyperglycaemia can lead to diabetic ketoacidosis. The first symptoms come on slowly over many hours or days. Additional symptoms include the following:
- nausea and/or vomiting
- abdominal pain
- rapid pulse
- heavy breathing
- moderate or large amounts of urine ketones. Ketones are produced when your body burns fat for energy instead of glucose.

If you have any of these symptoms and high sugars **get medical help immediately.**
See section 'If you forget to use Lyumjev'.

Illness
If you are ill, especially if you feel sick or are sick, the amount of insulin you need may change. **Even when you are not eating normally, you still need insulin.** Test your urine or blood, follow your 'sick rules', and tell your doctor.

5. How to store Lyumjev

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 label and the carton. The expiry date refers to the last day of that month.

Before first use
Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Keep in the outer carton in order to protect from light.

After first use (after cartridge insertion into the pen)
Do not store above 30 °C.
Do not freeze.
Do not refrigerate.

The pen with the inserted cartridge should not be stored with the needle attached.
Keep the cap on the pen in order to protect from light.
Discard after 28 days **even if some of the solution remains**.

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 to protect the environment.

6. Contents of the pack and other information

What Lyumjev 100 units/ml solution for injection in cartridge contains
- The active substance is insulin lispro. Each ml solution contains 100 units of insulin lispro. One cartridge contains 300 units of insulin lispro in 3 ml solution.
- The other ingredients are metacresol, glycerol, magnesium chloride hexahydrate, sodium citrate dihydrate, treprostinil sodium, zinc oxide, water for injections. Sodium hydroxide or hydrochloric acid may have been used to adjust the pH (see the end of section 2 under 'Lyumjev contains sodium').

What Lyumjev looks like and contents of the pack
Lyumjev 100 units/ml, solution for injection is a clear, colourless, aqueous solution in a cartridge.
Each cartridge contains 300 units (3 millilitres).

Pack sizes of 2, 5 or 10 cartridges.

Not all pack sizes may be marketed.

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