**Package leaflet: Information for the user**

**Humalog® 100 units/ml solution for injection in vial**
**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 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

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


## 1. What Humalog is and what it is used for

Humalog is used to treat diabetes. Humalog works more quickly than normal human insulin because the insulin molecule has been changed slightly.

You get diabetes if your pancreas does not make enough insulin to control the level of glucose in your blood. Humalog is a substitute for your own insulin and is used to control glucose in the long term. It works very quickly and lasts a shorter time than soluble insulin (2 to 5 hours). You should normally use Humalog within 15 minutes of a meal.

Your doctor may tell you to use Humalog as well as a longer-acting insulin. Each kind of insulin comes with another patient information leaflet to tell you about it. Do not change your insulin unless your doctor tells you to. Be very careful if you do change insulin.

Humalog is suitable for use in adults and children.

## 2. What you need to know before you use Humalog

**Do NOT use Humalog**
- if you think **hypoglycaemia** (low blood sugar) is starting. Further in this leaflet it tells you how to deal with mild hypoglycaemia (see Section 3: If you use more Humalog 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**
- Always check the pack and the vial label for the name and type of the insulin when you get it from your pharmacy. Make sure you get the Humalog that your doctor has told you to use.
- **If your blood sugar levels are well controlled by your current insulin therapy, you may not feel the warning** symptoms when your blood sugar is falling too low. Warning signs are listed later in this leaflet. 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 glucose often.

- A few people who have had hypoglycaemia after switching from animal insulin to human insulin have reported that the early warning symptoms were less obvious or different. If you often have hypoglycaemia or have difficulty recognising it, please discuss this with your doctor.
- If you answer YES to any of the following questions, tell your doctor, pharmacist or diabetes nurse
  - Have you recently become ill?
  - Do you have trouble with your kidneys or liver?
  - Are you exercising more than usual?
- The amount of insulin you need may also change if you drink alcohol.
- You should also tell your doctor, pharmacist or diabetes nurse if you are planning to go abroad. The time difference between countries may mean that you have to have your injections and meals at different times from when you are at home.
- Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who were treated with pioglitazone and insulin experienced the development of heart failure. Inform your doctor as soon as possible, if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema).

**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 very well if you inject into a lumpy area (See How to use Humalog). Contact your doctor if you are currently injecting into a lumpy area before you start injecting 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.

**Other medicines and Humalog**
Your insulin needs may change if you are taking
- the contraceptive pill,
- steroids,
- thyroid hormone replacement therapy,
- oral hypoglycaemics,
- acetyl salicylic acid,
- sulpha antibiotics,
- octreotide,
- "beta$_2$ stimulants" (for example ritodrine, salbutamol or terbutaline),
- beta-blockers, or
- some antidepressants (monoamine oxidase inhibitors or selective serotonin reuptake inhibitors),
- danazol,
- some angiotensin converting enzyme (ACE) inhibitors (for example captopril, enalapril), and
- angiotensin II receptor blockers.

Please tell your doctor, if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription (see section "Warnings and precautions").

**Pregnancy and breast-feeding**
Are you pregnant or thinking about becoming pregnant, or are you breast-feeding? The amount of insulin you need usually falls during the first three months of pregnancy and increases for the remaining six months. If you are breast-feeding, you may need to alter your insulin intake or diet. Ask your doctor for advice.

**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 operating machinery). You should contact your doctor about the advisability of driving if you have:
- frequent episodes of hypoglycaemia

- reduced or absent warning signs of hypoglycaemia

**Humalog 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 Humalog

Always use Humalog exactly as your doctor has told you. You should check with your doctor if you are not sure.

**Dose**
- You should normally inject Humalog within 15 minutes of a meal. If you need to, you can inject soon after a meal. But your doctor will have told you exactly how much to use, when to use it, and how often. These instructions are only for you. Follow them exactly and visit your diabetes clinic regularly.
- If you change the type of insulin you use (for example from a human or animal insulin to a Humalog product), 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.
- Inject Humalog under the skin. You should only inject it into a muscle if your doctor has told you to.

**Preparing Humalog**
- Humalog is already dissolved in water, so you do not need to mix it. But you must use it **only** if it looks like water. It must be clear, have no colour and no solid pieces in it. Check each time you inject yourself.

**Injecting Humalog**
- First wash your hands.
- Before you make an injection, clean your skin as you have been instructed. Clean the rubber stopper on the vial, but do not remove the stopper.
- Use a clean, sterile syringe and needle to pierce the rubber stopper and draw in the amount of Humalog you want. Your doctor or clinic will tell you how to do this. **Do not share your needles and syringes.**
- Inject under the skin, as you were taught. Do not inject directly into a vein. After your injection, leave the needle in the skin for five seconds to make sure you have taken the whole dose. Do not rub the area you have just injected. Make sure you inject at least half an inch (1 cm) from the last injection and that you 'rotate' the places you inject, as you have been taught. It doesn't matter which injection site you use, either upper arm, thigh, buttock or abdomen, your Humalog injection will still work quicker than soluble human insulin.
- Your doctor will tell you if you have to mix Humalog with one of the human insulins. For example if you do need to inject a mixture, draw the Humalog into the syringe before the long acting insulin. Inject the liquid as soon as you have mixed it. Do the same thing every time. You should not normally mix Humalog with one of the mixtures of human insulins. You should never mix Humalog with insulins produced by other manufacturers or animal insulins.
- You must not administer Humalog by the intravenous route. Inject Humalog as your physician or nurse has taught you. Only your physician can administer Humalog by the intravenous route. He will only do this under special circumstances such as surgery or if you are ill and your glucose levels are too high.

**Using Humalog in an infusion pump**
- Only certain CE-marked insulin infusion pumps may be used to infuse insulin lispro. Before infusing insulin lispro, the manufacturers instructions should be studied to ascertain the suitability or otherwise for the particular pump. Read and follow the instructions in the product literature supplied with the infusion pump.

- Be sure to use the correct reservoir and catheter for your pump.
- Changing of the infusion set (tubing and needle) must be done according to the instructions in the product information supplied with the infusion set.
- In the event of a hypoglycaemic episode, the infusion should be stopped until the episode is resolved. If repeated or severe low blood glucose levels occur, notify your doctor or clinic and consider the need to reduce or stop your insulin infusion.
- A pump malfunction or obstruction of the infusion set can result in a rapid rise in glucose levels. If an interruption to insulin flow is suspected, follow the instructions in the product literature and if appropriate, notify your doctor or clinic.
- When used with an insulin infusion pump, Humalog should not be mixed with any other insulin.

**If you use more Humalog than you should**
If you use more Humalog than you need or are unsure how much you have injected, a low blood sugar may occur. Check your blood sugar.

If your blood sugar is low **(mild hypoglycaemia)**, eat glucose tablets, sugar or drink a sugary drink. Then eat fruit, biscuits, or a sandwich, as your doctor has advised you and have some rest. This will often get you over mild hypoglycaemia or a minor insulin overdose. If you get worse and your breathing is shallow and your skin gets pale, tell your doctor at once. A glucagon injection can treat quite severe hypoglycaemia. Eat glucose or sugar after the glucagon injection. If you do not respond to glucagon, you will have to go to hospital. Ask your doctor to tell you about glucagon.

**If you forget to use Humalog**
If you take less Humalog than you need or are unsure how much you have injected, a high blood sugar may occur. Check your blood sugar.

If hypoglycaemia (low blood sugar) or hyperglycaemia (high blood sugar) is not treated they can be very serious and cause headaches, nausea, vomiting, dehydration, unconsciousness, coma or even death (see A and B in section 4 “Possible Side Effects”).

**Three simple steps** to avoid hypoglycaemia or hyperglycaemia are:
- Always keep spare syringes and a spare vial of Humalog.
- Always carry something to show you are diabetic.
- Always carry sugar with you.

**If you stop using Humalog.**
If you take less Humalog than you need, a high blood sugar may occur. Do not change your insulin unless your doctor tells you to.

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

## 4. Possible side effects

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

Systemic allergy is rare (≥ 1/10,000 to <1/1,000). The symptoms are as follows:
- rash over the whole body
- difficulty in breathing
- wheezing
- blood pressure dropping
- heart beating fast
- sweating.

If you think you are having this sort of insulin allergy with Humalog, tell your doctor at once.

Local allergy is common (≥ 1/100 to <1/10). Some people get redness, swelling or itching around the area of the insulin injection. This usually clears up in anything from a few days to a few weeks. If this happens to you, tell your doctor.

Lipodystrophy is uncommon (≥ 1/1,000 to <1/100). 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 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.

Oedema (e.g. swelling in arms, ankles; fluid retention) has been reported, particularly at the start of insulin therapy or during a change in therapy to improve control of your blood glucose.

**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**

**A. Hypoglycaemia**
Hypoglycaemia (low blood sugar) means there is not enough sugar in the blood. This can be caused if:
- you take too much Humalog 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; or
- you have trouble with your kidneys or liver which gets worse.

Alcohol and some medicines can affect your blood sugar levels.

The first symptoms of low blood sugar usually come on quickly and include the following:
- tiredness
- nervousness or shakiness
- headache
- rapid heartbeat
- feeling sick
- cold sweat.

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

**B. Hyperglycaemia and diabetic ketoacidosis**
Hyperglycaemia (too much sugar in the blood) means that your body does not have enough insulin. Hyperglycaemia can be brought about by:
- not taking your Humalog or other insulin;
- taking less insulin than your doctor tells you to;
- eating a lot more than your diet allows; or
- fever, infection or emotional stress.

Hyperglycaemia can lead to diabetic ketoacidosis. The first symptoms come on slowly over many hours or days. The symptoms include the following:
- feeling sleepy
- flushed face
- thirst
- no appetite
- fruity smell on the breath
- feeling or being sick

Severe symptoms are heavy breathing and a rapid pulse. **Get medical help immediately.**

**C. 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 Humalog

Before the first use store your Humalog in a refrigerator (2°C – 8°C). Do not freeze. Keep your vial in use in a refrigerator (2°C – 8°C) or at room temperature (below 30°C) and discard after 28 days. Do not put it near heat or in the sun.

Keep 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.

Do not use this medicine if you notice it is coloured or it has solid pieces in it. You must use it **only** if it looks like water. Check this each time you inject yourself.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. Contents of the pack and other information

**What Humalog 100 units/ml solution for injection in vial contains**

- The active substance is insulin lispro. Insulin lispro is made in the laboratory by a 'recombinant DNA technology' process. It is a changed form of human insulin and so is different from other human and animal insulins. Insulin lispro is closely related to human insulin which is a natural hormone made by the pancreas.
- The other ingredients are m-cresol, glycerol, dibasic sodium phosphate 7 $H_2O$, zinc oxide and water for injection. Sodium hydroxide or hydrochloric acid may have been used to adjust the acidity.

**What Humalog looks like and contents of the pack**

Humalog 100 units/ml solution for injection is a sterile, clear, colourless, aqueous solution and contains 100 units of insulin lispro in each millilitre (100 units/ml) solution for injection. Each vial contains 1000 units (10 millilitres). Humalog 100 units/ml solution for injection in vial comes in a pack of 1 vial, 2 vials or a multipack of 5 x 1 vial. Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Humalog 100 units/ml solution for injection in vial is made by:

- Lilly S.A., Avda. de la Industria 30, 28108 Alcobendas, Madrid, Spain.

The product licence is held by: Eli Lilly Nederland B.V., Orteliuslaan 1000, 3528 BD Utrecht, The Netherlands.

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

**United Kingdom**
Eli Lilly and Company Limited
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Detailed information on this medicine is available on the Medicines & Healthcare products Regulatory Agency website https:// www.mhra.gov.uk/