

HUMALOG® VIALS

Insulin Lispro (rbe)

Consumer Medicine Information

What is in this leaflet

This leaflet is designed to provide you with answers to some common questions about this medicine. It does not contain all the available information and does not take the place of talking with your doctor.

The information in this leaflet was last updated on the date shown on the final page. More recent information on this medicine may be available. Make sure you speak to your pharmacist, nurse or doctor to obtain the most up to date information on this medicine. You can also download the most up to date leaflet from www.lilly.com.au. The updated leaflet may contain important information about HUMALOG and its use that you should be aware of.

All medicines have risks and benefits. Your doctor has more information about this medicine than is contained in this leaflet. Also, your doctor has had the benefit of taking a full and detailed history from you and is in the best position to make an expert judgement to meet your individual needs.

If you have any concerns about using this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What HUMALOG is used for

HUMALOG is used to reduce high blood sugar (glucose) levels in patients with diabetes mellitus.

Diabetes is a condition in which your pancreas does not produce enough insulin to control your blood sugar level. Extra insulin is therefore needed.

There are two types of diabetes mellitus:

- Type 1 diabetes - also called Insulin Dependent Diabetes Mellitus (IDDM). Patients with type 1 diabetes always need insulin to control their blood sugar levels.
- Type 2 diabetes - also called Non Insulin Dependent Diabetes (NIDDM). Some patients with type 2 diabetes may also need insulin after initial treatment with diet, exercise and tablets.

HUMALOG is insulin lispro, which works more quickly than soluble insulin because the insulin molecule has been changed slightly.

The duration of effect of HUMALOG varies in each individual and also depends on dose, site of injection, blood supply, body temperature and physical activity.

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

Before using HUMALOG

Tell your doctor if you have any of the following conditions or if you have ever experienced any of these conditions.

When you must not use HUMALOG

Do not use/inject HUMALOG:

- **if you have had an allergic reaction to HUMALOG or to any of the ingredients listed at the end of this leaflet (see 'Product Description').** Signs of an allergic reaction include redness, swelling and itching at the injection site, rash, shortness of breath, fast pulse or sweating

- **if the packaging is torn or shows signs of tampering**
- **if you are experiencing low blood sugar (hypoglycaemia)**
- **if the vial appears frosted and the content is cloudy, thickened, coloured or has solid pieces in it**
- **if the expiry date (EXP) on the pack has passed.**

If you are not sure whether you should start using HUMALOG, talk to your doctor or pharmacist.

Before you start using HUMALOG

You must tell your doctor:

- **if you have had an allergic reaction to any medicine which you have used previously to treat your current condition.**
- **if you have or have had any medical conditions, especially kidney, liver or heart disease.**
- **if you experience fluid retention especially in the hands, ankles or feet.**
- **if you are pregnant or intend to become pregnant.** Pregnancy may make managing your diabetes more difficult. Insulin needs usually decrease during the first three months of pregnancy and increase during the last six months.

- **if you are breast-feeding or plan to breast-feed.**

It is not known if insulin HUMALOG is excreted in significant amounts in breast milk.

- **if you often have hypoglycaemia (low blood sugar) or if you have trouble recognising the symptoms of hypoglycaemia.** Under certain conditions the early warning signs of hypoglycaemia can be different or less pronounced.
- **if you drink alcohol.**
- **if you are ill.** Illness, especially with nausea and vomiting, may cause your insulin needs to change. Even if you are not eating, you still require insulin. You and your doctor should design an insulin plan for those times when you are sick.
- **if you are exercising more than usual.** Exercise may lower your need for insulin. Exercise may also speed up the effect of an insulin dose, especially if the exercise involves the area of injection site (eg. the leg should not be used for injection just prior to running).
- **Discuss with your doctor how much insulin you should use if you are exercising.**
- **if your diet changes.** Changes in diet may cause your insulin needs to change.

Tell your doctor about these things before you use HUMALOG.

Taking other medicines

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

Some medicines may affect the way HUMALOG works. These include:

- oral antidiabetic medicines
- medicines that affect your metabolism (corticosteroids such as prednisone, cortisone)
- medicines used for oral contraception
- medicines used in thyroid replacement therapy
- certain antibiotics used to treat tuberculosis, such as isoniazid
- medicines such as aspirin or other salicylates
- certain medicines used to treat depression
- certain medicines used to treat asthma, such as salbutamol or terbutaline
- medicines used to treat high blood pressure or other heart conditions
- certain medicines used to treat people with growth disorders and tumours, such as octreotide
- medicines used to treat hormone-related disorders, such as danazol
- thiazolidinediones (TZDs), also used to treat type 2 diabetes; when used with insulin there may be an increased risk of fluid retention and heart disease.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using HUMALOG.

Tell your doctor about these medicines before you use HUMALOG.

How to use HUMALOG vials

Carefully follow all directions given to you by your doctor or pharmacist.

These may differ from the information contained in this leaflet.

Your doctor may tell you to use HUMALOG with a longer acting human insulin such as HUMULIN NPH. A Consumer Medicine Information leaflet is also available for this product, ask your pharmacist.

There may be a delay in the effect of HUMALOG when it is mixed with HUMULIN NPH, compared to HUMALOG and HUMULIN NPH being injected separately.

HUMALOG should not be mixed with any other animal or human insulin preparations.

How much to use

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

Do not change your insulin unless your doctor tells you to. Be very careful if you do change insulin.

If you change the type of insulin that you use (for example from human insulin to HUMALOG), you may have to use more or less than before. This may happen with the first injection or it may be a gradual change over several weeks or months.

How to use HUMALOG in a syringe

Follow the steps below.

Preparing a dose

Check your vial. The solution in HUMALOG vials should be clear and colourless.

Check this before each injection.

1. Wash your hands.

- If using a new vial, flip off the protective plastic cap, but do not remove the stopper.
- Draw air into the syringe equal to the prescribed HUMALOG dose. Put the needle through the rubber top of the HUMALOG vial and inject air into the vial.
- Turn the vial and syringe upside down. Hold the vial and syringe firmly in one hand.
- Make sure the tip of the needle is in the HUMALOG solution and withdraw the correct dose into the syringe.
- Before removing the needle from the vial, check the syringe for air bubbles as these reduce the amount of HUMALOG in it. If bubbles are present, hold the syringe vertically and tap its side until the bubbles float to the top. Push them out with the plunger and withdraw the correct dose.
- Remove the needle from the vial and place the syringe down so that the needle does not touch anything.

Injecting a dose

- Wash your hands.
- Choose a site for injection. Use of injection sites should be rotated so that the same site is not used more than once a month.
- Stabilise the skin by spreading it or pinching up a large area. Insert the needle as instructed by your doctor.
- Push the plunger in as far as it will go.
- Pull the needle out and apply gentle pressure over the injection site for several seconds. Do not rub the area.
- Dispose of needles and syringes carefully. Needles and syringes must not be shared.

When to use it

Your doctor will tell you when to use HUMALOG.

You should normally use HUMALOG immediately (or up to 15 minutes) before a meal. When necessary, HUMALOG can be used soon after a meal. When HUMALOG is given after a meal, it must be given no later than 20 minutes after the start of the meal.

How to use HUMALOG in a subcutaneous infusion pump

- HUMALOG may be given under the skin by means of an insulin infusion pump. Use the type of pump system recommended by your doctor, read and follow the instructions that accompany your pump.
- HUMALOG should never be mixed with any other insulin when used in a pump.
- Before inserting the needle, wash your hands and the skin where the needle is to be inserted so as to prevent infection at the infusion site.
- When you are filling a new syringe, be certain not to leave large air bubbles in either the syringe or the catheter.
- Change the syringe and catheter after a maximum of 2 days' usage.
- Follow your doctor, nurse or pharmacist's advice about the basal infusion rate and the mealtime insulin boluses to be taken.
- To get the benefit of insulin infusion, and to detect possible malfunction of the insulin pump, you should measure your blood sugar levels regularly.

What to do in case of infusion pump system failure

In case of infusion pump system failure, you should always carry a spare vial of HUMALOG and a syringe, or an alternative insulin delivery system, for injection under the skin.

How long do I use it

Do not stop using HUMALOG just because you feel better. It is important that you do not stop using HUMALOG unless your doctor tells you.

If you inject too much

Low blood sugar (hypoglycaemia) is the most likely reaction if you have injected more HUMALOG than you need. Symptoms of mild to moderate hypoglycaemia can include:

- sweating
- hunger, headache
- tremor, unsteady movement
- lightheadedness
- drowsiness, dizziness
- depressive mood, anxiety
- irritability, personality change
- abnormal behaviour
- inability to concentrate
- sleep disturbance
- blurred vision
- increased heart rate or irregular heart beat
- tingling in the hands/feet/lips or tongue
- slurred speech.

Recognising these mild to moderate hypoglycaemic symptoms early may allow you to take the necessary steps to avoid more serious hypoglycaemia. Symptoms of severe hypoglycaemia can include:

- disorientation
- seizures
- unconsciousness.

If you experience symptoms of low blood sugar, eat some sugary food or drink, such as jelly beans, orange juice or glucose tablets.

If you do not feel better after eating/drinking some sugary food or drink, contact your doctor or go to the Emergency Department at your nearest hospital.

While you are using HUMALOG

Things you must do

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

While you are using HUMALOG, tell your doctor or pharmacist before you start any new medicine.

If you become pregnant while using HUMALOG, tell your doctor.

Always carry a supply of vials and syringes with you.

Always carry something to show you have diabetes.

Always carry glucose or sugary food with you.

Things you must not do

Do not stop using HUMALOG without first checking with your doctor.

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

Your doctor has prescribed HUMALOG specifically for you.

Do not share needles, vials or syringes.

Do not reuse syringes.

Things to be careful of

- if you become ill
- if you are exercising more than usual
- if your diet changes.

You should learn to recognise your own symptoms of hypoglycaemia (low blood sugar).

You can then take the appropriate action, when necessary. If you are having problems recognising these symptoms, frequent monitoring of your blood sugar level is recommended.

Side effects

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

Like other medicines, HUMALOG may cause some unwanted side effects. These are likely to vary from patient to patient. Some side effects may be related to the dose of your insulin.

Tell your doctor as soon as possible about any unwanted effects.

Your doctor may then decide to adjust the dose of insulin you are taking.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Tell your doctor if you experience any of the following side effects:

- Hypoglycaemia**
The most common unwanted effect when using insulin, including HUMALOG, is low blood sugar (hypoglycaemia). If untreated, severe hypoglycaemia may lead to unconsciousness and, in extreme cases, death.
If you experience symptoms of low blood sugar (hypoglycaemia), eat some sugary food or drink, such as jellybeans, orange juice or glucose tablets.
If you do not feel better after eating/drinking some sugary food or drink, contact your doctor or go to the Emergency Department at your nearest hospital.
- Local Allergy** - Some patients occasionally experience redness, swelling and itching at the injection site. Sometimes this local allergy may be due to factors other than your insulin, such as irritants in the skin cleansing agent or poor injection technique.
If you have local allergic reactions while using HUMALOG contact your doctor.
- Generalised Allergy** - Generalised allergy is less common, but can be more serious than local allergies. Symptoms of generalised allergy include: rash over the whole body, shortness of breath, wheezing, reduction in blood pressure, fast pulse or sweating. Severe cases of generalised allergy may be life threatening.
If you think you are having a generalised allergic reaction to HUMALOG, tell a doctor immediately or go to the Emergency Department at your nearest hospital.

4. Lipodystrophy - A depression in the skin or an enlargement or thickening of the tissue can develop at the injection site.

Tell your doctor if you notice these symptoms.

A change in the way you inject and rotating the injection site may help relieve these symptoms.

5. Oedema - Fluid retention, particularly in the ankles, feet and hands.

Tell your doctor if you notice anything unusual or if you are concerned about any aspect of your health, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

After using HUMALOG

Storage

Keep your HUMALOG vials in a fridge between 2°C - 8°C. Do not freeze HUMALOG.

The vial being used can be kept below 30°C for up to 28 days. Do not put it near heat or in the sun.

Do not use a vial after the expiry date (month, year) stamped on the label.

All medicines should be kept where young children cannot reach them.

Disposal

If your doctor tells you to stop using HUMALOG or you find your vials have passed their expiry date, please return any left over vials to your pharmacist.

Needles should be disposed of in a sharps container or similar puncture proof container composed of hard plastic or glass.

Ask your doctor, nurse or pharmacist where you can dispose of the container once it is full.

Product Description

What it looks like

HUMALOG is available in 10 mL vials. The carton and label have a maroon stripe.

HUMALOG is a clear, colourless solution.

Ingredients

HUMALOG contains 100 units of insulin lispro per mL. It also contains meta-Cresol, glycerol, sodium phosphate dibasic, zinc oxide and water for injection.

Supplier

Supplied in Australia by:

Eli Lilly Australia Pty. Limited
112 Wharf Road
WEST RYDE NSW 2114

Supplied in New Zealand by:

Eli Lilly and Company (NZ) Ltd
Level 1, 123 Ormiston Rd
South Botany, Auckland
New Zealand

Australian Registration Number:

HUMALOG Vials - AUST R 53488.

Further Information

You can get more information about diabetes and insulin from:

Diabetes Australia

- freecall helpline 1300 136 588
- www.diabetesaustralia.com.au

Diabetes New Zealand

- toll free helpline 0800 DIABETES (0800 342 238)
- www.diabetes.org.nz

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