

HUMALOG[®], HUMALOG[®] MIX25 and HUMALOG[®] MIX50 KwikPen

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 these medicines. 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 these medicines 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 these medicines, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What the HUMALOG insulins are used for

HUMALOG insulins are used to reduce high blood sugar (glucose) levels in insulin dependent diabetic patients.

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 mellitus (NIDDM). Some patients with type 2 diabetes may also need insulin after initial treatment with diet, exercise and tablets.

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

HUMALOG MIX25 is 25% insulin lispro and 75% insulin lispro protamine sulfate suspension. This means that the action of HUMALOG MIX25 is prolonged.

HUMALOG MIX50 is 50% insulin lispro and 50% insulin lispro protamine suspension. This means that the action of HUMALOG MIX50 is prolonged.

The duration of effect of HUMALOG insulins 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 insulins

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 the HUMALOG insulins

Do not use/inject HUMALOG insulins:

- **if you have had an allergic reaction to HUMALOG, HUMALOG MIX25 or HUMALOG MIX50, 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 HUMALOG solution is cloudy, thickened, coloured or has solid pieces in it.**
- **if HUMALOG MIX25 or HUMALOG MIX50 suspension is no longer cloudy white after gentle shaking or if it has solid pieces in it.**
- **if the cartridge in the KwikPen appears frosted.**

This can occur when solid white particles stick to the bottom and walls.

- **if the expiry date (EXP) on the pack has passed.**

HUMALOG MIX25 or HUMALOG MIX50 should not be given intravenously.

The use of HUMALOG MIX25 and HUMALOG MIX50 has not been studied in children under the age of 18.

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

Before you start using HUMALOG insulins

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 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 (e.g. 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 insulins.

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 your HUMALOG insulin 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 insulins.

Tell your doctor about these medicines before you use HUMALOG insulins.

How to use HUMALOG insulins

Follow all directions given to you by your doctor or pharmacist carefully.

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.

More frequent monitoring of your blood sugar level is recommended when changing insulin dose or type.

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.

Your doctor will tell you the type of HUMALOG that is best suited to you.

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 take 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 it

Inject HUMALOG, HUMALOG MIX25 or HUMALOG MIX50 under the skin. Under no circumstances should HUMALOG MIX25 or HUMALOG MIX50 be given intravenously.

Follow the steps below.

Preparing a dose

1. Remove Pen Cap and check the cartridge in your KwikPen. The solution of HUMALOG should be clear and colourless. The suspension in HUMALOG MIX25 and HUMALOG MIX50 KwikPens should be white and cloudy or milky.
2. **HUMALOG MIX25 and HUMALOG MIX50 KwikPens must be rolled between the palms ten times and inverted ten times until the contents are uniformly mixed. Do not shake vigorously as this may cause frothing which may interfere with the correct measurement of the dose.**
3. Inspect the KwikPen for uniform mixing and repeat the above steps if necessary.

If HUMALOG MIX25 or HUMALOG MIX50 KwikPens appear "frosted", please return to the place of purchase for exchange. This can occur when solid white particles stick to the bottom and walls.

Check your KwikPen before each injection.

4. Wash your hands.

The manufacturer's instructions for the KwikPen insulin delivery system should be followed for preparing and priming the KwikPen, attaching the needle and administering the insulin injection.

Check for insulin flow (Priming)

1. Set the dose to 2 units.
2. Hold the KwikPen with the needle pointing up and tap the side of the pen so that any bubbles float to the top.
3. With the KwikPen still pointing up, press the Dose Knob in until it stops and 0 is seen in the Dose Window. Hold Dose Knob in and count slowly for 5 seconds. Priming is complete when a stream of insulin comes out of the needle. This is very important to ensure the correct dose is injected.
4. Only after seeing a stream of insulin at the needle tip can you proceed to dial up your required dose. There may still be some small air bubbles left in the pen. These are harmless, but if the air bubble is too big, it may make the dose of your injection less accurate.

Injecting a dose

1. Wash your hands.

2. Choose a site for injection. Use of injection sites should be rotated so that the same site is not used more than approximately once a month
3. Remove outer needle cap.
4. Stabilise the skin by spreading it or pinching up a large area. Insert the needle as instructed by your doctor.
5. Press the Dose Knob and push firmly until the Dose Knob stops moving. Count to 5 slowly before removing the needle from the skin.
6. Pull the needle out and apply gentle pressure over the injection site for several seconds. Do not rub the area.
7. Using the outer needle cap, unscrew the needle and dispose of it safely. Do not reuse the needle. **NEEDLES and PENS MUST NOT BE SHARED.**

Further injections

1. Check your KwikPen before each injection. Ensure HUMALOG MIX25 and HUMALOG MIX50 contents are uniformly mixed, as described in 'Preparing a Dose'.
2. Before every injection, check for insulin flow. Do this by dialling 2 units and pressing the Dose Knob with the pen pointing up. Do this until a stream of insulin comes out of the needle.
3. Stop using the KwikPen if the correct dose can no longer be dialled. The KwikPen will not allow you to dial a dose

greater than the number of insulin units remaining in the cartridge in the KwikPen.

4. You can see how much insulin is left by looking at the gauge on the side of the cartridge in the KwikPen. The scale on the cartridge shows how many units you have left. If there is not enough for your dose, you may either:
 - a. Give the partial dose and then give the remaining dose using a new KwikPen.

Or

- b. Give the full dose with a new KwikPen.

Do not mix any other insulin in your pen. Once the pen is empty, do not use it again.

When to use it

Your doctor will tell you when to use your HUMALOG insulin.

You should normally use HUMALOG, HUMALOG MIX25 or HUMALOG MIX50 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 within 20 minutes of the start of the meal.

How long do I use it

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

If you inject too much

Low blood sugar (hypoglycaemia) is the most likely reaction if you have injected more insulin 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 insulins

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are using HUMALOG or HUMALOG MIX25, HUMALOG MIX50.

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

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

Always carry a supply of your HUMALOG insulin pens with you.

Always carry something to show you have diabetes.

Always carry glucose or sugary foods with you.

Always check for insulin flow before injecting a dose.

Immediately after an injection, remove the needle from the pen.

This will ensure sterility and prevent leakage, re-entry of air and potential needle clogs.

Things you must not do

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

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

Your doctor has prescribed your HUMALOG insulin specifically for you.

Do not share needles or pens.

Do not reuse needles.

Do not inject HUMALOG MIX25 or HUMALOG MIX 50 directly into a vein (intravenously).

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 any of the HUMALOG insulins.

Like other medicines, HUMALOG insulins 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 so it is important that you never exceed the stated dose.

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

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

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:

1. Hypoglycaemia - The most common unwanted effect when using insulin, including HUMALOG insulins, 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 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.

2. 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 insulins contact your doctor.

3. 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 any HUMALOG insulin, 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 insulins

Storage

Keep your pens in a fridge between 2°C - 8°C. Do not freeze any of these HUMALOG insulins.

You may keep the pens below 30°C for up to 28 days while you are using them. Do not put your pens near heat or in the sun. Do not keep the pre-filled pen that you are using in the fridge.

Do not use a pen 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 insulins or you find your pens have passed their expiry date, please return any leftover pens to your pharmacist.

Empty pens and 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 3 mL prefilled pens in a maroon carton.

HUMALOG is a clear colourless solution.

HUMALOG MIX25 is available in 3 mL prefilled pens in a yellow carton.

The suspension in HUMALOG MIX25 pens is white and cloudy or milky.

HUMALOG MIX50 is available in 3 mL prefilled pens in a red carton.

The suspension in HUMALOG MIX50 pens is white and cloudy or milky.

Ingredients

All KwikPens in the HUMALOG range contain 100 units of insulin lispro per mL.

HUMALOG also contains metacresol, glycerol, dibasic sodium phosphate heptahydrate, zinc oxide and water for injection.

HUMALOG MIX25 and HUMALOG MIX50 also contains metacresol, phenol, glycerol, dibasic sodium phosphate

heptahydrate, protamine sulfate, zinc oxide and water for injection.

Supplier

Supplied in Australia by:

Eli Lilly Australia Pty. Limited

112 Wharf Road

WEST RYDE NSW 2114

Australian Registration Numbers:

HUMALOG KwikPens -AUST R 64214

HUMALOG MIX25 KwikPens - AUST R 69164

HUMALOG MIX50 KwikPens - AUST R 69167

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

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

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