

# HUMALOG<sup>®</sup> /HUMALOG<sup>®</sup> MIX25/HUMALOG<sup>®</sup> MIX50 KwikPens

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using HUMALOG insulin?

HUMALOG insulins contain the active ingredient **insulin lispro (rbe)**. HUMALOG insulins are used to **reduce high blood sugar (glucose) levels** in patients with diabetes. For more information, see Section [1. Why am I using HUMALOG insulin?](#) in the full CMI.

### 2. What should I know before I use HUMALOG insulin?

Do not use if you have ever had an allergic reaction to insulin lispro or any of the ingredients listed at the end of the CMI or when you have low blood sugar.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use HUMALOG insulin?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with HUMALOG insulins and affect how they work. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use HUMALOG insulin?

- Your doctor will tell you what dose of HUMALOG insulin you need to use each day.
- Do not inject HUMALOG MIX 25 or HUMALOG MIX50 directly into your veins (intravenously).

More instructions can be found in Section [4. How do I use HUMALOG insulin?](#) in the full CMI.

### 5. What should I know while using HUMALOG insulin?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, pharmacist, and diabetes educator you visit that you are using HUMALOG insulin.</li><li>• Monitor your blood sugar levels regularly.</li><li>• Always carry some glucose or sugary foods with you in case you get low blood sugar.</li><li>• Tell your doctor if you become pregnant or start breastfeeding while using HUMALOG insulin.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using or change your dose of HUMALOG insulin without first checking with your doctor.</li><li>• Do not use HUMALOG insulins when you have low blood sugar as it will make it worse.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Low blood sugar may impair your ability to concentrate or react while driving. Do not drive if you feel like your blood sugar levels are low.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol. Alcohol may mask the symptoms of low blood sugar.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your pens in a fridge between 2°C - 8°C. Do not freeze.</li><li>• You may keep the pens below 30°C for up to 28 days while using them. Dispose after 28 days.</li><li>• Do not keep the pen that you are using in the fridge.</li></ul>

For more information, see Section [5. What should I know while using HUMALOG insulins?](#) in the full CMI.

### 6. Are there any side effects?

The most common (and potentially the most severe) side effect of HUMALOG insulins is low blood sugar.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# HUMALOG<sup>®</sup> /HUMALOG<sup>®</sup> MIX25/HUMALOG<sup>®</sup>

## MIX50 KwikPens

Active ingredient: *insulin lispro (rbe)*

### Consumer Medicine Information (CMI)

This leaflet provides important information about using HUMALOG insulins. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using HUMALOG insulins.**

Where to find information in this leaflet:

- [1. Why am I using HUMALOG insulin?](#)
- [2. What should I know before I use HUMALOG insulin?](#)
- [3. What if I am taking other medicine?](#)
- [4. How do I use HUMALOG insulin?](#)
- [5. What should I know while using HUMALOG insulin?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using HUMALOG insulin?

HUMALOG insulins contain the active ingredient **insulin lispro (rbe)**.

There are 3 different types of HUMALOG insulins available in KwikPens:

- HUMALOG
- HUMALOG MIX25
- HUMALOG MIX50

They all contain the same active ingredient but **HUMALOG** is a solution whereas **HUMALOG MIX25** and **HUMALOG MIX50** are pre-mixed suspensions. Each will vary with how long they work in your body.

HUMALOG insulins are used **to reduce high blood sugar (glucose) levels** in patients with diabetes.

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:

**Type 1 diabetes** - patients with type 1 diabetes always need insulin to control their blood sugar levels.

**Type 2 diabetes** - some patients with type 2 diabetes may also need insulin after initial treatment with diet, exercise, and tablets.

### 2. What should I know before I use HUMALOG insulin?

#### Warnings

**Do not use HUMALOG insulins:**

- if you are allergic to insulin lispro, or any of the ingredients listed at the end of this leaflet. Always

check the ingredients to make sure you can use this medicine.

- when you have hypoglycaemia (low blood sugar).
- **HUMALOG MIX25** and **HUMALOG MIX50** should not be used intravenously.

**Check with your doctor if you:**

- have had an allergic reaction to any medicine which you have used previously to treat diabetes.
- are using, or have used, another type or brand of insulin. This may affect the dose of HUMALOG insulin that you are prescribed.
- have or have had kidney or liver disease. This may affect the dose of HUMALOG insulin that you are prescribed.
- have or have had heart disease and are also taking thiazolidinediones, a type of medicine used to treat type 2 diabetes (such as pioglitazone, rosiglitazone). You may be more at risk to develop fluid retention (oedema) especially in the hands, ankles, or feet, or heart failure while using HUMALOG insulin.
- are taking any other medications.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

**Check with your doctor if you are pregnant or intend to become pregnant.** Pregnancy may make managing diabetes more difficult. Insulin needs usually decrease during the first three months of pregnancy and increase during the last six months.

**Talk to your doctor if you are breastfeeding or intend to breastfeed.** It is not known if HUMALOG insulins are excreted in significant amounts in breast milk.

#### Children (under 18 years)

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

### 3. What if I am taking other medicines?

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

**You may need a lower dose of HUMALOG insulin if you are also taking any of the following medicines:**

- other medicines that treat diabetes
- aspirin or other salicylates

- a group of antibiotics, known as sulfonamides, used to treat infections
- certain medicines used to treat depression, such as monoamine oxidase inhibitors
- certain medicines used to treat high blood pressure or other heart conditions such as captopril, enalapril, angiotensin II receptor blockers, and beta blockers.
- certain medicines used to treat people with growth disorders and tumours, such as octreotide.

You may need a **higher dose** of HUMALOG insulin if you are also taking any of the following medicines:

- medicines used for oral contraception ('the pill')
- medicines that affect your metabolism (corticosteroids such as prednisone and cortisone)
- medicines used in thyroid replacement therapy
- certain antibiotics used to treat tuberculosis, such as isoniazid
- beta-2 stimulants, a group of medicines used to treat asthma (such as salbutamol or terbutaline)
- certain medicines used to treat schizophrenia, bipolar disorder, or nausea and vomiting, such as phenothiazines
- certain medicines used to treat hormone-related disorders, such as danazol.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins, or supplements you are taking and if these affect HUMALOG insulins.**

## 4. How do I use HUMALOG insulin?

### How much to use

Your doctor will tell you what dose of HUMALOG insulin you need to use each day.

### When to use HUMALOG insulin

- Your doctor will tell you when to use HUMALOG insulin.
- You should normally use HUMALOG insulins immediately (or up to 15 minutes) **before a meal**.
- When necessary, HUMALOG can be used **within 20 minutes after the start of a meal**. Do not use HUMALOG MIX25 or HUMALOG MIX50 after the start of a meal.

### How to use HUMALOG insulins

Read the instructions for use leaflet contained in the carton carefully before using the HUMALOG, HUMALOG MIX25 or HUMALOG MIX50 KwikPen.

- Check to make sure that you are the correct insulin. This is especially important if you use more than one type of insulin.
- **HUMALOG** should look clear and colourless. **Do not use if it is cloudy, coloured, or has particles or clumps in it.**
- **HUMALOG MIX25** and **HUMALOG MIX50** should look white and cloudy after mixing. **Do not use if it looks clear or contains any lumps or particles.**

- HUMALOG insulins are injected under the skin (subcutaneously) of your stomach area or upper legs. **Use of injection sites should be rotated** so that the same spot is not used more than approximately once a month.
- **HUMALOG MIX25 and HUMALOG MIX50 should not be injected directly into your veins (intravenously).**

### If you forget to use HUMALOG insulin

#### Test your blood sugar level as soon as possible.

If you use less HUMALOG insulin than you need, a high blood sugar level (hyperglycaemia) may occur.

Use it as soon as you remember, and then go back to using it as you would normally. **Do not use a double dose of HUMALOG insulin.**

If you are unsure, talk to your doctor, diabetes educator, or pharmacist.

### If you use too much HUMALOG insulin

Hypoglycaemia (low blood sugar) may occur if you have used more HUMALOG insulin than you need. 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. This will often resolve mild hypoglycaemia or a minor insulin overdose.

If you get worse and your breathing is shallow and your skin gets pale, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using HUMALOG insulin?

### Things you should do

- Remind any doctor, dentist, pharmacist or diabetes educator you visit that you are using HUMALOG insulin.
- Monitor your blood sugar levels regularly to ensure that your dose of HUMALOG insulin is appropriate. More frequent monitoring is recommended when changing insulin dose or type, or when you start taking a new medicine.
- Always carry a supply of HUMALOG insulin KwikPens.
- Always carry something to show you have diabetes.
- Always carry glucose or sugary foods in case you develop hypoglycaemia (low blood sugar).

### Tell your doctor

- if you become pregnant or start breastfeeding while using HUMALOG insulin.

- if you notice changes to your eyesight. This may be a sign that your diabetes is not being controlled appropriately.
- Tell your doctor, pharmacist, or diabetes educator if you plan to travel. You may need to carry a letter explaining why you are taking injecting devices with you. Your doctor, pharmacist, or diabetes educator can provide you with some helpful information.

### Things you should not do

- Do not use HUMALOG insulins when you have hypoglycaemia (low blood sugar) as it will make it worse.
- Do not stop using HUMALOG insulin without first checking with your doctor.
- Do not change your insulin (dose or type) 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 HUMALOG insulin specifically for you.
- Do not mix HUMALOG insulin with any other animal or human insulin preparations.
- **Do not share needles or pens.**
- **Do not re-use needles.**
- Do not store your insulin pen with the needle attached. This will ensure that your insulin will not become contaminated, and prevent leakage, the re-entry of air, and potential needle clogs.
- Do not use HUMALOG insulin if the packaging is torn or shows signs of tampering.
- Do not use **HUMALOG** if the solution is cloudy, thickened, coloured, or has solid pieces in it, as it may no longer be good to use.
- Do not use **HUMALOG MIX25** or **HUMALOG MIX50** if the suspension is no longer cloudy white after gentle shaking or if it has solid pieces in it, as it may no longer be good to use.
- Do not use HUMALOG insulin if the cartridge in the KwikPen appears frosted, as it may no longer be good to use.
- Do not use HUMALOG insulin if you think it has been frozen or exposed to excessive heat. It will not work as well.

### Hypoglycaemia (low blood sugar)

Your blood sugar level may become too low if you:

- use too much HUMALOG insulin
- exercise too much or excessively
- delay eating meals or snacks
- eat too little food
- are ill.

Symptoms of **mild to moderate** hypoglycaemia can come on suddenly, and may include:

- weakness, trembling or shaking
- sweating
- light headedness/headache
- lack of concentration
- behaviour change

- dizziness
- tearfulness/crying
- irritability
- numbness around the lips/fingers
- hunger

**Tell your doctor if you have trouble recognising these symptoms, if you often have hypoglycaemia or if you have ever become unconscious after using insulin.** More frequent monitoring of your blood sugar level may be recommended, or your dose may need to be changed.

Recognising these mild to moderate symptoms early may allow you to take the necessary steps to avoid more serious hypoglycaemia.

#### **Always carry some sugary food or drink with you.**

If you experience symptoms of mild to moderate hypoglycaemia, immediately eat some sugary food or drink, such as jelly beans, fruit 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.**

**Tell your relatives, friends, close workmates, or carers that you have diabetes.**

It is important that they also recognise the signs and symptoms of hypoglycaemia.

Make sure they know to give you some sugary food or drink for mild to moderate symptoms of hypoglycaemia.

**Severe** symptoms of hypoglycaemia may include:

- disorientation
- seizures, fits, or convulsions
- loss of consciousness.

**If you lose consciousness, make sure your relatives, friends, close workmates, or carers know:**

- to turn you on your side and **get medical help immediately.**
- not to give you anything to eat or drink to avoid choking.

Severe hypoglycaemia can lead to unconsciousness and in extreme cases death if not treated.

An injection of the hormone glucagon may speed up recovery from unconsciousness. This can be given by a relative, friend, workmate, or carer who knows how to give it.

If glucagon is used, have some sugary food or drink as soon as you are conscious again.

### Hyperglycaemia (high blood sugar)

Your blood sugar levels may become too high if you:

- miss doses of HUMALOG insulin or use less than you need
- have uncontrolled diabetes
- exercise less than usual
- eat more carbohydrates than usual
- are ill or stressed.

**Contact your doctor if your blood sugar level is too high and you experience any of the following.** High blood sugar

levels over a long period of time can lead to too much acid in the blood (diabetic ketoacidosis).

Symptoms of mild to moderate hyperglycaemia may include:

- drowsiness
- flushed face
- thirst, loss of appetite
- fruity odour on the breath
- blurred vision
- passing larger amounts of urine than usual
- getting up at night more often than usual to pass urine
- nausea and vomiting.

**Contact your doctor or the Emergency Department immediately if your blood sugar level is too high and you experience any of the following severe symptoms.** Severe hyperglycaemia can lead to unconsciousness and in extreme cases death (if left untreated).

Symptoms of severe hyperglycaemia:

- heavy breathing
- fast pulse
- nausea, vomiting
- nausea and vomiting where you cannot keep any fluids down (leading to severe dehydration)
- loss of consciousness.

## Illness

**Tell your doctor 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.

## Emotional disturbances

**Tell your doctor if you are feeling particularly excited, upset, or stressed.**

Emotional disturbances may impact your dose of HUMALOG insulin.

## Exercise

Exercise may lower your need for insulin. Exercise may also make insulin work more quickly, especially if the exercise involves the area around the injection site (e.g., the leg should not be used as an injection site prior to jogging or running).

**Tell your doctor if you are exercising more than usual, as your dose of HUMALOG insulin may need to change.**

## Diet

Changes to your diet may cause your insulin needs to change.

**Tell your doctor before making any significant changes to your diet (e.g., removing carbohydrates).**

## Injection site

If you inject HUMALOG insulin in the same place, the fatty tissue may shrink (lipoatrophy) or thicken (lipohypertrophy).

Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis).

To help prevent these skin changes, **do not use the same place for injection more often than once a month.**

HUMALOG insulin may not work very well if you inject into a lumpy, shrunken, or thickened area. **Avoid injecting into these areas.**

**Tell your doctor if you are currently injecting into these affected areas before you start injecting in a different area.**

Your doctor may tell you to measure your blood sugar more frequently, and to adjust your dose of HUMALOG insulin or other antidiabetic medications.

## Driving or using machines

**Be careful before you drive or use any machines or tools until you know how HUMALOG insulins affect you.**

**Do not drive if you feel like your blood sugar level is low.**

Hypoglycaemia (low blood sugar) may impair your ability to concentrate or react while driving.

## Drinking alcohol

**Tell your doctor if you drink alcohol.**

Alcohol may mask the symptoms of hypoglycaemia (low blood sugar) and make it more difficult to recognise them.

Alcohol may also affect the dose of HUMALOG insulin that you are prescribed.

## Looking after your medicine

- Keep your pens in a fridge between 2°C - 8°C. Do not freeze.
- While in-use, do not keep the pens in the fridge. You may keep them at unrefrigerated (below 30°C) for up to 28 days.
- Dispose of unrefrigerated pens after 28 days even if they still contain insulin.
- Do not store the pens in the bathroom or near a sink.
- Do not put the pens near heat or in the sun.
- **Keep it where young children cannot reach it.**

## When to discard your medicine

Discard pens after the expiry date (month, year) stamped on the label has passed.

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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, pharmacist or diabetes educator where you can dispose of the container once it is full.**

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Blood sugar related:</b></p> <ul style="list-style-type: none"> <li>• <b>Mild to moderate hypoglycaemia</b> (low blood sugar), symptoms may include: <ul style="list-style-type: none"> <li>o weakness, trembling or shaking</li> <li>o sweating</li> <li>o light headedness/headache</li> <li>o lack of concentration</li> <li>o behaviour change</li> <li>o dizziness</li> <li>o tearfulness/crying</li> <li>o irritability</li> <li>o numbness around the lips/fingers</li> <li>o hunger</li> </ul> </li> </ul>	<p><b>Immediately eat some sugary food or drink, such as jelly beans, fruit juice or glucose tablets.</b></p> <p><b>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.</b></p>
<p><b>Allergy related:</b></p> <ul style="list-style-type: none"> <li>• <b>Local allergy</b>, symptoms may include redness, swelling and itching around the injection site. These symptoms generally resolve within days to a few weeks of continued use.</li> </ul> <p><b>Skin related:</b></p> <ul style="list-style-type: none"> <li>• <b>Lipodystrophy</b>, symptoms may include a depression in the skin or an enlargement or thickening of the tissue around the injection site. <ul style="list-style-type: none"> <li>o A change in injection technique may help resolve the problem.</li> </ul> </li> </ul> <p><b>General:</b></p> <ul style="list-style-type: none"> <li>• <b>Oedema (fluid retention)</b>, particularly in the ankles, feet and hands.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>Blood sugar related:</b></p> <ul style="list-style-type: none"> <li>• <b>Severe hypoglycaemia</b> (low blood sugar), symptoms may include: <ul style="list-style-type: none"> <li>o disorientation</li> <li>o seizures, fits, or convulsions</li> <li>o loss of consciousness.</li> </ul> </li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p> <p><b>If you lose consciousness, caregivers should turn you on your side and get medical help immediately. They should not give you anything to eat or drink to avoid choking.</b></p>
<p><b>Allergy related:</b></p> <ul style="list-style-type: none"> <li>• <b>Generalised allergy</b>, symptoms may include: <ul style="list-style-type: none"> <li>o rash over a large part of the body</li> <li>o shortness of breath</li> <li>o wheezing</li> <li>o low blood pressure</li> <li>o swelling of the face, lips, or tongue</li> <li>o fast pulse</li> <li>o sweating</li> </ul> </li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

HUMALOG insulins are only available with a doctor's prescription.

### What HUMALOG insulins contain

<b>Active ingredient (main ingredient)</b>	insulin lispro (100 units per mL)
<b>Other ingredients (inactive ingredients)</b>	<p><b>HUMALOG</b></p> <ul style="list-style-type: none"><li>• dibasic sodium phosphate heptahydrate</li><li>• glycerol</li><li>• hydrochloric acid</li><li>• metacresol</li><li>• sodium hydroxide</li><li>• water for injection</li><li>• zinc oxide</li></ul> <p><b>HUMALOG MIX25 and HUMALOG MIX50</b></p> <ul style="list-style-type: none"><li>• dibasic sodium phosphate heptahydrate</li><li>• glycerol</li><li>• hydrochloric acid</li><li>• metacresol</li><li>• phenol</li><li>• protamine sulfate</li><li>• sodium hydroxide</li><li>• water for injection</li><li>• zinc oxide</li></ul>

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**Do not take this medicine if you are allergic to any of these ingredients.**

### What HUMALOG insulins look like

#### HUMALOG KwikPen (AUST R 64214)

HUMALOG is available in 3 mL pre-filled KwikPens.

HUMALOG is a clear colourless solution.

#### HUMALOG MIX25 KwikPen (AUST R 69164)

HUMALOG MIX25 is available in 3 mL pre-filled KwikPens.

HUMALOG MIX25 is a white and cloudy or milky suspension.

#### HUMALOG MIX50 KwikPen (AUST R 69167)

HUMALOG MIX50 is available in 3 mL pre-filled pens.

HUMALOG MIX50 is a white and cloudy or milky suspension.

### Who distributes HUMALOG insulins?

#### **Supplied in Australia by:**

Eli Lilly Australia Pty Ltd  
Level 9, 60 Margaret Street  
SYDNEY NSW 2000