PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

HUMALOG 100 units/ml solution for injection

Insulin lispro

Read all of this leaflet carefully before you start using HUMALOG

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- HUMALOG has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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

Each ml of HUMALOG contains 100 units insulin lispro.

HUMALOG is used to treat diabetes. 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.

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 are hypersensitive (allergic) to insulin lispro or any of the other ingredients of HUMALOG (listed in section 6).
- If you are experiencing hypoglycaemia (low blood sugar).

Warnings and precautions:

- 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.
- 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.
- Any change of insulin should be made cautiously and only under medical supervision.
- If you suffer from kidney or liver impairment, your dose may need to be adjusted.
- If you have recently become ill or are exercising more than usual, your dose may need to be adjusted.

- If you are taking pioglitazone together with HUMALOG, it may increase the risk of oedema (e.g. swelling in arms, ankles; fluid retention) and heart failure, especially in patients with existing heart disease.
- Your insulin needs may change if you are taking other medicines e.g. the contraceptive pill, corticosteroids, thyroid replacement therapy, oral anti-diabetic medicines, salicylates, sulpha antibiotics, certain anti-depressants and certain anti-hypertensive (blood pressure medication). Speak to your doctor when using other medication in addition to HUMALOG.
- 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.
- HUMALOG solution should be clear and colourless. Do not use the HUMALOG solution if it appears cloudy, thickened or slightly coloured or if solid particles are visible.
- After you prepare your dose, you should administer it promptly to avoid clogging of the 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 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

Always tell your healthcare professional if you are taking any other medicines. (This includes complementary or traditional medicines.)

- You may require more insulin when using medicines with hyperglycaemic (high blood sugar) activity, such as the contraceptive pill, corticosteroids or thyroid replacement therapy.
- Your insulin requirements may be decreased in the presence of certain medicines such as oral anti-diabetic agents, salicylates, sulpha antibiotics, octreotide, "beta$_2$ stimulants (for example ritodrine, salbutamol or terbutaline), certain anti-depressants (such as monoamine oxidase inhibitors or selective reuptake inhibitors), and certain anti-hypertensive (low blood pressure) medicines such as some angiotensin converting enzyme (ACE) inhibitors (for example captopril, enalapril) or angiotensin II receptor blockers.

Please consult a healthcare professional when using other medication in addition to HUMALOG.

HUMALOG with food and drink

Carefully follow your doctor's instructions regarding food intake with the use of HUMALOG.

Pregnancy and, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

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 breastfeeding, you may need to alter your insulin or diet.

Driving and using machines

Your ability to concentrate and react may be reduced if you have hypoglycaemia. Please keep this 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 medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e., essentially "sodium-free"

3. How to use HUMALOG

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.

Before starting therapy, you should read the "User Manual" that accompanies the delivery device, to ensure the correct use thereof.

Do not share medicines prescribed for you with any other person.

Always take HUMALOG exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with HUMALOG will last. Do not stop treatment early. If you have the impression that the effect of HUMALOG is too strong or too weak, tell your doctor or pharmacist.

General directions for use:

You should normally inject HUMALOG within 15 minutes of a meal. If you need to, you can inject soon after a meal. Your doctor will tell you exactly how much to use, when to use it and how often. These instructions are only for you. Follow them exactly.

- If you change the type of insulin you use (for example from a human or animal to HUMALOG), 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 subcutaneously (under the skin). You should inject either the upper arms, thighs, buttocks, or abdomen. The injection sites must be rotated so that the same site is not used more than once a month.

Injecting HUMALOG

Vials

- 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 site 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.
- Care should be taken to ensure that you do not inject directly into a vein. Inject HUMALOG as your doctor or nurse has taught you. Only your doctor can administer HUMALOG by the intravenous route under special circumstances such as surgery or if you are ill and your glucose levels are too high.

To prevent the possible transmission of disease, each pen and cartridge must be used by you only.

Mixing of Insulins

- HUMALOG may be used together with a longer-acting insulin or in combination with oral sulphonylurea agents on the advice of a medical practitioner.
- HUMALOG may be mixed with HUMULIN N on advice of the medical practitioner.
- HUMALOG should be drawn into the syringe first, to prevent contamination of the vial by the longer-acting insulin.
- It is advisable to inject immediately after mixing.
- Mixing of insulin must only be done using HUMALOG vials and not the cartridges.

Cartridge

You must only use HUMALOG cartridges in Lilly insulin pens. Please make sure that HUMALOG or Lilly cartridges are mentioned in the leaflet accompanying your pen. The 3 ml cartridge only fits the 3 ml pen.

The instructions with each individual pen must be followed for loading the cartridge, attaching the needle and administering the insulin injection.

Kwikpen

The pre-filled pen has to be used as recommended in the user manual.

Pens should not be used if any part looks broken or damaged.

Injecting a dose

The following is a general description.

1. Wash your hands

2. Choose a site for injection.

3. Clean the skin as instructed.

4. Use a clean needle (needles are not included).

5. Stabilise the skin by spreading it or pinching up a large area. Insert the needle and inject as instructed.

6. Pull the needle out and apply gentle pressure over the injection site for several seconds. Do not rub the area.

7. As soon as you have done the injection, unscrew the needle from the KwikPen using the outer needle cap. This will keep the insulin sterile and stop it leaking. It also stops air entering the pen and your needle clogging. **Do not share your needles**. Do not share your pen. Replace the cap on your pen.

8. Use of the injection sites should be rotated so that the same is not used more than approximately once a month.

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 manufacturer's instructions should be studied to verify 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 take more HUMALOG than you should

- Overdosage causes hypoglycaemia (low blood sugar) with accompanying symptoms that include listlessness (lack of interest and energy), confusion, palpitations (rapid irregular action of the heart), headache, sweating and vomiting.
- 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.
- 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.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison centre.

If you forget to use HUMALOG

- If you take less HUMALOG than you need, your blood sugar levels may increase. Check your blood sugar and consult your doctor, pharmacist, or other healthcare professional.
- Do not take a double dose to make up for forgotten individual doses.
- If hypoglycaemia (low blood sugar) is not treated it can be very serious and cause headaches, nausea, vomiting, dehydration, unconsciousness (see section 4 “Possible Side Effects”).

If you stop using HUMALOG

- If you take less HUMALOG than you need, your blood sugar levels may increase. Check your blood sugar and consult your doctor, pharmacist, or other healthcare professional. Do not change your insulin unless your doctor tells you to.

4. Possible side effects

- HUMALOG can have side effects.
- Not all side effects reported for HUMALOG are included in this leaflet.
- Should your general health worsen or if you experience any untoward effects while taking HUMALOG, please consult your health care provider for advice.

If any of the following happens, stop using HUMALOG and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Rash over the whole body
- Shortness of breath, wheezing
- Reduction in blood pressure
- Fast pulse

- Sweating

These are all serious side effects. If you have them, you may have a serious reaction to HUMALOG. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- Hypoglycaemia (low blood sugar). This is the most frequent side effect.
- Allergic reaction (local allergy). Redness, swelling and itching can occur at the site of insulin injection.
- Lipodystrophy (thickening or pitting of the skin). 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 the arms, ankles; fluid retention) has been reported, particularly at the start of insulin therapy or during a change in therapy.

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the **Med Safety APP (Medsafety X SAHPRA)** and **eReporting platform (who-umc.org)** found on SAHPRA website. Alternatively, report suspected side effects to the company at ade_za@lilly.com. By reporting side effects, you can help provide more information on the safety of HUMALOG.

5. How to store HUMALOG

Do not freeze. Do not expose to excessive heat or sunlight.

Before use

Store in a refrigerator (2 °C – 8 ºC).

After first use/after cartridge insertion

Vials

If refrigeration is not possible, the vial in use can be stored unrefrigerated at or below 30 ºC for 28 days.

Cartridge

Store at or below 30 °C and discard after 28 days. Do not refrigerate. The pen with the inserted cartridge should not be stored with the needle attached.

KwikPen

Store at or below 30 °C and discard after 28 days. Do not refrigerate. The pre-filled pen should not be stored with the needle attached.

Do not use product after the expiry date.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What HUMALOG contains

The active ingredient is insulin lispro.

The other ingredients are metacresol, glycerol, dibasic sodium phosphate (heptahydrate), zinc oxide, water for injections. Hydrochloric acid and sodium hydroxide may be used to adjust pH.

What HUMALOG looks like and contents of the pack

The vials, cartridges and disposable pens contain a sterile, clear, colourless solution for injection, free from particulate matter.

Vials: A 10 ml, clear, transparent, colourless Type I flint-glass vial, sealed with a rubber stopper and secured with an aluminium seal, packed into outer cardboard cartons. Available in packs of 1.

Cartridges: A 3,0 ml, clear, transparent, colourless Type I flint-glass cartridge sealed with a red rubber plunger head at the bottom of the cartridge and a rubber disc with outer red aluminium seal at the top of the cartridge.

Cartridges are packed into plastic blisters. Blisters are packed into an outer cardboard carton. Available in packs of 5.

Disposable pens: Pre-filled, disposable pen injectors containing 3,0 ml cartridges are packed into an outer cardboard carton. Available in packs of 5.

Holder of the Certificate of Registration

Eli Lilly (S.A.) (Pty) Ltd

First Floor, Golden Oak House, Ballyoaks Office Park,

35 Ballyclare Drive,

Bryanston, 2191

Johannesburg,

RSA.

This leaflet was last revised on

31 March 2025

Registration number

29/21.1/0785

Registration Details for Botswana		
Humalog 10ml vial	Reg. No.: BOT9700137	Schedule 2
Humalog 3ml Prefilled Pens (KwikPens)	Reg. No.: BOT9700137A	Schedule 2
Humalog 3ml cartridges	Reg. No.: BOT9700137B	Schedule 2
Please report any suspected ADRs to BoMRA through e-reporting https://primaryreporting.who-umc.org/BW and e-mail reportadr@bomra.co.bw.		

Registration Details for Namibia		
Humalog 10ml vial	Reg. No.: 04/21.1/0646	Schedule NS2
Humalog 3ml Prefilled Pens (KwikPens)	Reg. No.: 04/21.1/0646	Schedule NS2
Humalog 3ml cartridges	Reg. No.: 04/21.1/0646	Schedule NS2