

**Patient Leaflet in Accordance with the Pharmacists' Regulations (Preparations)**  
**- 1986**

The dispensing of this medicine requires a doctor's prescription

**HUMALOG KWIKPEN 200 units/ml**  
**Solution for Injection in a pre-filled pen**

**Active ingredient and its quantity:**

Each pen contains:  
insulin lispro 200 units/ml

**Each KwikPen delivers 1-60 units in steps of 1 unit.**

**Inactive ingredients and allergens:** See section 2, "Important information about some of the ingredients of this medicine" and section 6 "Additional Information".

**Read this patient leaflet carefully in its entirety before using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, please contact your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

**1. What is this Medicine Intended for?**

For the treatment of adults who have diabetes and need insulin to maintain a balanced blood sugar level.

In addition, **Humalog KwikPen** is indicated for initial diabetes control.

**Therapeutic group:** Insulins and rapid-acting insulin analogs.

**Humalog KwikPen 200 units/ml** is used to treat diabetes. Humalog works more quickly than normal human insulin because insulin lispro has been changed slightly in comparison to human insulin. Insulin lispro is closely related to human insulin which is a natural hormone made by the pancreas.

You get diabetes if your pancreas does not make enough insulin to control the level of glucose in your blood. **Humalog KwikPen** 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 KwikPen 200 units/ml** 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 KwikPen 200 units/ml** should be reserved for the treatment of adults with diabetes requiring daily doses of more than 20 units of rapid-acting insulin.

The KwikPen is a disposable pre-filled pen containing 3 ml (600 units, 200 units/ml) of insulin lispro. One KwikPen contains multiple doses of insulin. The KwikPen dials 1 unit at a time. **The number of units are displayed in the dose window, always check this before your injection.** You can give from 1 to 60 units in a single injection. **If your dose is more than 60 units, you will need to give yourself more than one injection.**

## **2. Before Using this Medicine**

### **Do not use this medicine if:**

- you are sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (see section 6).
- you think **hypoglycemia** (low blood sugar) is starting. Further in this leaflet it tells you how to deal with mild hypoglycemia (see section 3: If you use more Humalog than you should).

### **Special warnings regarding the use of this medicine:**

- Always check the pack and the label of the pre-filled pen for the name and type of the insulin when you get it from your pharmacy. Make sure you get the **Humalog KwikPen 200 units/ml** that your doctor has told you to use.
- **The Humalog KwikPen 200 units/ml solution for injection in your pre-filled pen should ONLY be injected with this pre-filled pen. Do not transfer the insulin lispro from your Humalog KwikPen 200 units/ml to a syringe.** The markings on the insulin syringe will not measure your dose correctly. A severe overdose can result, causing low blood sugar which may put your life in danger. Do not transfer insulin from your **Humalog KwikPen 200 units/ml** to any other insulin delivery devices like insulin infusion pumps.
- **Do NOT mix the Humalog KwikPen 200 units/ml solution for injection in your pre-filled pen (the KwikPen) with any other insulin or any other medicine.** The medicine should not be diluted.
- 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 in section 4 of 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 hypoglycemia after switching from animal insulin to human insulin have reported that the early warning symptoms were less obvious or different. If you often have hypoglycemia or have difficulty recognizing 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?
- 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 localized swelling (edema).
- This Pen is not recommended for use by the blind or visually impaired without the help of someone trained to use the Pen.

### **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 the medicine?'). 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.

### **Drug Interactions**

**If you are taking or have recently taken other medicines, including nonprescription medications and nutritional supplements, inform your doctor or pharmacist.**

Your insulin needs may change if you are taking

- the contraceptive pill
- steroids
- thyroid hormone replacement therapy
- oral hypoglycemics (e.g. metformin, acarbose, sulphonylurea agents, pioglitazone, empagliflozin, DPP-4-inhibitors like sitagliptin and saxagliptine)
- acetyl salicylic acid
- sulpha antibiotics
- somatostatin analogues (such as octreotide, used to treat an uncommon condition in which you make too much growth hormone)
- "beta<sub>2</sub> stimulants" (such as salbutamol or terbutaline to treat asthma, or ritodrine used to stop premature labor)
- beta-blockers - to treat high blood pressure
- some antidepressants (monoamine oxidase inhibitors or selective serotonin reuptake inhibitors)
- danazol (medicine acting on ovulation)
- some angiotensin converting (ACE) inhibitors, used to treat certain heart conditions or high blood pressure (for example captopril and enalapril)
- specific medicines to treat high blood pressure, kidney damage due to diabetes, and some heart problems (angiotensin II receptor blockers).

### **Use of this medicine and alcohol consumption**

Your blood sugar levels may either rise or fall if you drink alcohol. Therefore, the amount of insulin needed may change.

### **Pregnancy and breastfeeding**

Are you pregnant or thinking about becoming pregnant, or are you breastfeeding? 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 intake or diet. Ask your doctor for advice.

### **Driving and using machines**

Your ability to concentrate and react may be reduced if you have hypoglycemia. 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 using machines). You should contact your doctor about the advisability of driving if you have:

- frequent episodes of hypoglycemia
- reduced or absent warning signs of hypoglycemia

### **Important information about some of the ingredients of this medicine**

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

### **3. How to Use this Medicine?**

Always use this medicine as instructed by your doctor. You must check with your doctor or pharmacist if you are not sure.

The dosage and manner of treatment will be determined by the doctor only. **Do not exceed the recommended dose.**

To prevent the possible transmission of disease, each pen must be used by you only, even if the needle is changed.

**Humalog KwikPen 200 units/ml** is intended for patients taking more than 20 units of rapid-acting insulin a day.

**Do not transfer insulin from your Humalog KwikPen 200 units/ml to a syringe. The markings on the insulin syringe will not measure your dose correctly. A severe overdose can result, causing low blood sugar which may put your life in danger.**

Do not use **Humalog KwikPen 200 units/ml** solution for injection in an insulin infusion pump.

### **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 (subcutaneously).

### **Preparing Humalog KwikPen 200 units/ml**

- 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 color and no solid pieces in it. Check each time you inject yourself.

### **Getting the KwikPen ready to use (Please see user manual)**

- First wash your hands.
- Read the instructions on how to use your pre-filled insulin pen. Please follow the instructions carefully. Here are some reminders.
- Use a clean needle (needles are not included).
- Prime your KwikPen before each use. This checks that insulin comes out and clears the air bubbles from your KwikPen. There may still be some small air bubbles left in the pen - these are harmless. But if the air bubbles are too large it may affect the insulin dose.

### **Injecting Humalog**

- Before you make an injection, clean your skin as you have been instructed. Inject under the skin, as you were taught. 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 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.
- Do not inject **Humalog KwikPen 200 units/ml** directly into a vein (intravenously).

### **After injecting**

- 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.

### **Further injections**

- Every time you use a KwikPen you must use a new needle. Before every injection, clear any air bubbles. You can see how much insulin is left by holding the KwikPen with the needle pointing up.
- Once the KwikPen is empty, do not use it again. Please get rid of it carefully - your pharmacist or diabetes nurse will tell you how to do this.

### **If you use more Humalog than 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 hypoglycemia**), 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 hypoglycemia 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 hypoglycemia. Eat glucose or sugar after the glucagon injection. If you do not respond to glucagon, you will have to go to the hospital. Ask your doctor to tell you about glucagon.

**If you forgot to inject Humalog**, you may experience high blood sugar levels. Check your blood sugar levels.

If hypoglycemia (low blood sugar) or hyperglycemia (high blood sugar) is not treated, they can be very severe and cause headaches, nausea, vomiting, dehydration, unconsciousness, coma and even death (see Section 4 – side effects).

**Three simple steps** to avoid hypoglycemia or hyperglycemia are:

1. Always carry a spare pen in case you lose your KwikPen or it gets damaged.
2. Always carry something to show you are diabetic.
3. 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.

**Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.**

**If you have any further questions regarding the use of this medicine, consult the doctor or pharmacist.**

### **4. Side Effects**

As with any medicine, the use of **Humalog KwikPen 200 units/ml** may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Severe allergy is rare (may affect up to 1 in 1,000 people). 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, contact a doctor at once.

Local allergy is common (may affect up to 1 in 10 people). 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 (may affect up to 1 in 100 people). 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.

Edema (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.

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, you should consult the doctor.

### **Reporting side effects**

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting side effects due to drug treatment" that can be found on the Home Page of the Ministry of Health's website ([www.health.gov.il](http://www.health.gov.il)), which refers to an online form for reporting side effects, or by entering the following link:  
<https://sideeffects.health.gov.il>

### **Common problems of diabetes**

#### **Hypoglycemia**

Hypoglycemia (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 diarrhea or vomiting)
- there is a change in your need for insulin
- you have trouble with your kidneys or liver which gets worse

Alcohol and some medicines can affect your blood sugar levels (see section 2).

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 recognizing your warning symptoms, avoid situations such as driving a car, in which you or others would be put at risk by hypoglycemia.

### **Hyperglycemia and diabetic ketoacidosis**

Hyperglycemia (too much sugar in the blood) means that your body does not have enough insulin.

Hyperglycemia 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
- fever, infection or emotional stress

Hyperglycemia 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.**

### **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 this Medicine?**

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Before opening, store refrigerated at 2°C-8°C. Do not freeze. Do not expose to excessive heat or direct sunlight.
- Keep your **Humalog KwikPen 200 units/ml** in use at room temperature (below 30°C) and discard after 28 days. Do not put it near heat or in the sun. Do not keep the KwikPen that you are using in the fridge.
- The KwikPen should not be stored with the needle attached.
- Do not use this medicine if you notice the solution is colored 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. Additional Information**

**In addition to the active ingredient, Humalog KwikPen 200 units/ml also contains:**

Glycerol, trometamol, metacresol, zinc oxide, water for injections, HCL solution, NaOH solution.

### **What does the medicine look like and contents of the pack:**

**Humalog KwikPen 200 units/ml** is a sterile, clear, colorless, aqueous solution and contains 200 units of insulin lispro in each milliliter (200 units/ml) solution for

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injection. Each **Humalog KwikPen 200 units/ml** contains 600 units (3 milliliters). **Humalog KwikPen 200 units/ml** comes in a pack of 2 or 5 pre-filled pens. Not all pack sizes may be marketed.

**Registration holder:** Eli Lilly Israel Ltd., 4 HaSheizaf St., P.O.Box 4246, Ra'anana  
**Name of manufacturer and address:** Lilly France, Fegersheim, France.

**Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 155-39-34483-00

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