

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a physician's prescription only

HUMALOG KWIKPEN 100 units/ml
Solution for injection in a Junior pre-filled pen

Active ingredient and its quantity:

Each pen contains:

insulin lispro 100 units/ml

Each Junior KwikPen enables an injection of 0.5 – 30 units in steps of 0.5 unit.

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

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, 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 and children with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis.

In addition, **Humalog Junior KwikPen** is indicated for the initial stabilization of diabetes mellitus.

Therapeutic group: Drugs used in diabetes, insulins and analogues for injection, fast-acting.

- **Humalog Junior KwikPen** 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 Junior 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 Junior KwikPen** within 15 minutes of a meal.
- Your doctor may tell you to use **Humalog Junior KwikPen** 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 Junior KwikPen is suitable for use in adults and children.

The **Junior KwikPen** is a disposable pre-filled pen containing 3 ml (300 units, 100 units/ml) of insulin lispro. One **Junior KwikPen** contains multiple doses of insulin. The **Junior KwikPen** dials half unit (0.5 unit) at a time. **The number of units are displayed in the dose window, always check this before your injection.** You can give from 0.5 unit to 30 units in a single injection. **If your dose is more than 30 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 (insulin lispro) or any of the other ingredients of this medicine (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 have accidentally taken a higher dose).

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 Junior KwikPen 100 units/ml** that your doctor has told you to use.
- **Do NOT mix the Humalog 100 units/ml solution for injection in your pre-filled pen (the Junior KwikPen) with any other insulins or any other medicines.**
- 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, consult 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 consult 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 section “How should you use this 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 (see section “Special warnings regarding the use of this medicine”).

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 or 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)
- ‘beta₂ 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 (MAOIs) or selective serotonin reuptake inhibitors (SSRIs)]
- danazol (medicine acting on ovulation)

- some angiotensin converting (ACE) inhibitors, used to treat certain heart conditions or high blood pressure (for example captopril, 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

If you are pregnant, thinking about becoming pregnant or breastfeeding, consult your doctor.

The amount of insulin you need usually falls during the first trimester of pregnancy and increases for the remaining six months.

If you are breastfeeding, you may need to alter your insulin intake or diet. Consult your doctor.

Driving and using machines

Your ability to concentrate and react may be reduced if you have hypoglycemia.

Keep this possible problem in mind in all situations where you might put yourself and others at risk (e.g. driving a car or operating machinery).

You should consult 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 SHOULD YOU USE THIS MEDICINE?

Always use this preparation according to the doctor's instructions. You must check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with this preparation. To prevent the possible transmission of disease, each pen must be used by you only, even if the needle is changed.

Dose

The dosage and manner of treatment will be determined only by the doctor.

Do not exceed the recommended dose.

- The number of half units (0.5 units) is shown in the dose window of your pen. The half units (0.5 units) are shown as lines between the numbers.
- Always check the number in the dose window to make sure you have dialed the correct dose.
- You should normally inject **Humalog Junior KwikPen** 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 Junior KwikPen**), 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.
- **Humalog Junior KwikPen** is only suitable for injecting just under the skin. Speak to your doctor if you need to inject your insulin by another method.

Preparing Humalog Junior KwikPen

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 Junior KwikPen ready to use (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 new needle (needles are not included).
- Prime your **Junior KwikPen** before each use. This checks that insulin comes out and clears the air bubbles. 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 Junior KwikPen

- Before you make an injection, clean your skin as you have been instructed. 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 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 Junior KwikPen** injection will still work quicker than soluble human insulin.
- You must not administer **Humalog Junior KwikPen** by the intravenous route. Inject **Humalog Junior KwikPen** as your physician or nurse has taught you. Only your physician can administer **Humalog Junior KwikPen** by the intravenous route. He will only do this under special circumstances such as surgery or if you are ill and your glucose levels are too high.

After injecting

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

Further injections

- Every time you use a **Humalog Junior 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 **Junior KwikPen** with the needle pointing up. The scale on the cartridge shows about how many units you have left.
- Once the **Humalog Junior KwikPen** is empty, do not use it again. Get rid of it carefully - your pharmacist or diabetes nurse will tell you how to do this.

Using Humalog Junior KwikPen in an infusion pump

- **Junior KwikPen** is only suitable for injecting just under the skin. Do not use the pen to administer **Humalog Junior KwikPen** by a different way. Other forms of **Humalog** 100 units/ml are available if this is necessary. Speak to your doctor if this applies to you.

If you have accidentally taken a higher dose of Humalog Junior KwikPen than you should or you 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 use the medicine

If you take less Humalog Junior KwikPen than you need or are unsure how much you have injected, a high blood sugar may occur. Check your blood sugar.

If hypoglycemia (low blood sugar) or hyperglycemia (high blood sugar) is not treated they can be very serious and cause headaches, nausea, vomiting, dehydration, unconsciousness, coma or even death (see section 4 - Side Effects).

Three simple steps to avoid hypoglycemia or hyperglycemia are:

- Always carry a spare pen in case you lose your **Junior KwikPen** or it gets damaged.
- Always carry something to show you are diabetic.
- Always carry sugar with you.

Treatment should be continued as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with this medicine without consulting the doctor.

If you stop using the medicine

If you take less **Humalog Junior KwikPen** 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 a 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

Like all medicines, this medicine can cause side effects in some users. Do not be alarmed while 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 users) and 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 Junior KwikPen**, tell your doctor at once.

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

Reporting of 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), which refers to the online form for reporting side effects, or via the following link: <https://sideeffects.health.gov.il>

Common problems of diabetes

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 “Use of this medicine and alcohol consumption”).

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 (nausea) or are sick (vomiting), 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.

If a side effect appears, if any side effect gets worse, or if you suffer from a side effect not mentioned in this leaflet, you should consult the doctor.

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Before the first use store your **Humalog Junior KwikPen** in a refrigerator (2°C-8°C). Do not freeze.
- Keep your **Humalog Junior KwikPen** in use at room temperature (below 30°C) and discard after 28 days, **even if some of the solution remains.** Do not put it near heat or in the sun. Do not keep the **Humalog Junior KwikPen** that you are using in the fridge. The **Humalog Junior KwikPen** should not be stored with the needle attached.
- Do not use this medicine if you notice the solution is coloured or it has solid pieces in it. You must use it **only** if it looks like water. Check this each time you inject yourself.

- This medicine should not be disposed of via wastewater or household waste. Ask the 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, this medicine also contains:

Glycerol, metacresol, dibasic sodium phosphate, zinc oxide, HCL solution 10%, NaOH solution 10%, water for injections.

What does the medicine look like and what are the contents of the pack:

Humalog Junior KwikPen is a sterile, clear, colorless, aqueous solution and contains 100 units of insulin lispro in each milliliter. Each **Humalog Junior KwikPen** contains 300 units (3 milliliters). The **Humalog Junior KwikPen** comes in a pack of 5 pre-filled pens.

Registration holder name and address: Eli Lilly Israel Ltd., 4 HaSheizaf st., POB 4246, Ra'anana 4366411, Israel.

Manufacturer and address: Eli Lilly & Company Ltd., Indianapolis, Indiana, USA

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Registration number of the medicine in the National Drug Registry of the Ministry of Health:

143-44-33216-00