

Patient Communication

IMPORTANT SAFETY INFORMATION FOR Humalog® 200 units/ml KwikPen™ (insulin lispro)

Dear Patient,

This letter is provided to give you important information about the safe and correct use of your new Humalog 200 units/ml KwikPen (insulin lispro). Before using this product, please make sure you read the provided Humalog 200 units/ml KwikPen Package Leaflet and User Manual for more information.

What is Humalog?

- Humalog is a rapid-acting (mealtime) insulin used to treat diabetes. It works by reducing your blood sugar level.
- Humalog solution for injection is available in 2 strengths. This is the amount of Humalog in units per millilitre (ml):
 - 100 units/ml and
 - 200 units/ml

What is Humalog 200 units/ml KwikPen?

- KwikPen is a disposable pre-filled pen designed to deliver Humalog by subcutaneous injection (injection under the skin).
- Humalog 100 units/ml solution for injection is available in vials, cartridges and the KwikPen.
- Humalog 200 units/ml solution for injection is available ONLY in the pre-filled pen (the Humalog 200 units/ml KwikPen).
- Humalog 200 units/ml KwikPen has twice as many insulin units in each ml than Humalog 100 units/ml KwikPen.

What you need to know before you use Humalog 200 units/ml KwikPen

- Inject Humalog 200 units/ml solution for injection ONLY by the KwikPen in which it is supplied.
- DO NOT draw up Humalog 200 units/ml solution for injection from the KwikPen using an insulin syringe. The markings on insulin syringes will not measure your dose correctly.
- Using Humalog 200 units/ml solution for injection in any other type of delivery device, like an insulin syringe or an insulin infusion pump, may result in an overdose causing severe low blood sugar and MAY PUT YOUR LIFE IN DANGER.
- The dose indicator on the Humalog 200 units/ml KwikPen should always be used to select the dose. The Humalog 200 units/ml KwikPen will deliver the exact dose that is dialled.
- Do not convert your dose if you change from one Humalog strength to the other. This may lead to under or over dosing resulting in high or low blood sugar.

- Check how many units have been dialled on the Humalog 200 units/ml KwikPen before injecting the dose.
- When you receive your insulin, always check the package and the label of the pen for the name, type and strength of the insulin. Make sure you receive the Humalog 200 units/ml KwikPen that your healthcare professional has told you to use.

How to identify Humalog 200 units/ml KwikPen

- The carton for the Humalog 200 units/ml KwikPen contains the following design features which will help you to be sure to have the correct medicine:
 - A yellow warning box containing the wording: “Use only in this pen, or severe overdose can result”
 - The strength of 200 units/ml is written in a yellow box.
 - Background colour is dark grey instead of white for the Humalog 100 units/ml KwikPen.
- The pre-filled pen itself contains the following design features which will help you to be sure to have the correct pen:
 - The pen colour is dark grey.
 - The label of the pen is burgundy and contains a checkered box.
 - The strength of 200 units/ml is written in a yellow box.

Call for reporting

To report medication errors, adverse events or product complaints among patients taking Humalog 200 units/ml KwikPen, please contact Lilly at: +353 1 661 4377

Alternatively, medication errors, adverse event or product complaint information may be reported to the Health Products Regulatory Authority (HPRA):

Phone: +353 1 6764971

e-mail: medsafety@hpra.ie

Mail: Pharmacovigilance Section, Health Products Regulatory Authority, Earlsfort Centre, Earlsfort Terrace, Dublin 2

Online: www.hpra.ie

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, product brand name, strength and batch number

This message is not meant to provide a complete description of the risks related to the use of the Humalog 200 units/ml KwikPen. Before using this product, please make sure you read the provided Humalog 200 units/ml KwikPen *Package Leaflet* and *User Manual* for more information. If you have any questions about your Humalog 200 units/ml KwikPen, contact your healthcare professional for help or Lilly at: +353 1 661 4377.