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Direct Healthcare Professional Communication on the correct use of Humalog (insulin lispro) 200 units/ml KwikPen to minimize medication errors

Dear Healthcare Professional,
This letter is to inform you of important safety information regarding insulin lispro, a mealtime insulin analogue now available in a strength of 200 units/ml (Humalog® 200 units/ml KwikPen™), for the treatment of diabetes mellitus in adults.

Summary

- **Insulin lispro 200 units/ml solution for injection should ONLY be administered using the Humalog 200 units/ml prefilled pen (KwikPen).**
- **Transfer of the higher strength insulin lispro 200 units/ml from the Humalog 200 units/ml KwikPen to a different insulin delivery system may lead to overdose and severe hypoglycaemia.**
- **It is important to make patients using the Humalog 200 units/ml KwikPen aware of this risk and instruct them NOT to transfer insulin from Humalog 200 units/ml KwikPen to a syringe or insulin pump for administration.**
- **When switching from one Humalog strength to another, the dose does not need to be converted – the dose-counter window on both pens displays the number of units of insulin lispro to be injected. Unnecessary dose conversion may lead to under/over dosing and resultant hyper/hypoglycaemia.**
- **When prescribing Humalog KwikPen please ensure that the correct strength is clearly written on the prescription.**
- **Please provide the attached patient communication for Humalog 200 units/ml KwikPen to all patients receiving their first prescription. Please call +353 1 661 4377 to obtain more copies of the patient communication. To retrieve or print the patient communication, go to the HPRA website: www.hpra.ie/homepage/medicines/safety-information/educational-material**

Further information on the safety concern and the recommendations

The European Commission has approved the Humalog 200 units/ml KwikPen for the treatment of adults with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis.

Humalog 200 units/ml KwikPen should be reserved for patients taking more than 20 units of rapid-acting insulin per day.

The Humalog 200 units/ml KwikPen contains 600 units of insulin lispro in 3 ml solution for injection, which is twice the concentration of standard 100 units/ml mealtime insulin. The maximum amount of insulin lispro which can be given in one injection from the Humalog 200 units/ml KwikPen is 60 units.

The carton containing the Humalog 200 units/ml KwikPen includes the following design features which will help to differentiate this carton from the carton of the Humalog 100 units/ml KwikPen:

- 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 color is dark grey instead of white for the Humalog 100 units/ml KwikPen.

Images of the new Humalog 200 units/ml Kwikpen are below. Please advise new patients on the Humalog 200 units/ml design features using these images.

Humalog 200 units/ml KwikPen outer carton

The Humalog 200 units/ml prefilled pen contains the following design features which will help to differentiate this pen from the Humalog 100 units/ml KwikPen:

- The pen color 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.

Humalog 200 units/ml KwikPen

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 HPRA:

Phone: +353 1 6764971
Mail: Pharmacovigilance Section, Health Products Regulatory Authority, Earlsfort Centre, Earlsfort Terrace, Dublin
e-mail: medsafety@hpra.ie
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.

Company contact point

This letter is not intended as a complete description of the risks associated with the use of Humalog 200 units/ml KwikPen. Please refer to the attached Summary of Product Characteristics (SPC) for a complete description of risks.

Please contact Lilly at: +353 1 661 4377, if you have any questions about the information in this letter or the safe and effective use of Humalog 200 units/ml KwikPen.

Yours faithfully,

Dr Greg Van Wyk
Medical Director
Eli Lilly and Company Limited

enclosure: Patient communication, Humalog 200 units/ml KwikPen SPC