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Direct Healthcare Professional Communication on the correct use of Humalog 200 units/ml KwikPen (insulin lispro) 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 pre-filled pen (KwikPen).**
- **Instruct patients using the Humalog 200 units/ml KwikPen NOT to transfer the insulin lispro contained to a different delivery system, because overdose and serious hypoglycaemia could result.**
- **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.** [to retrieve, or print the patient communication, go to the eMC (electronic Medicines Compendium) website at www.medicines.org.uk]

Further information on the safety concern and 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 requiring more than 20 units of rapid-acting insulin per day. Please read the attached Summary of Product Characteristics (SPC) for full details of use.

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.

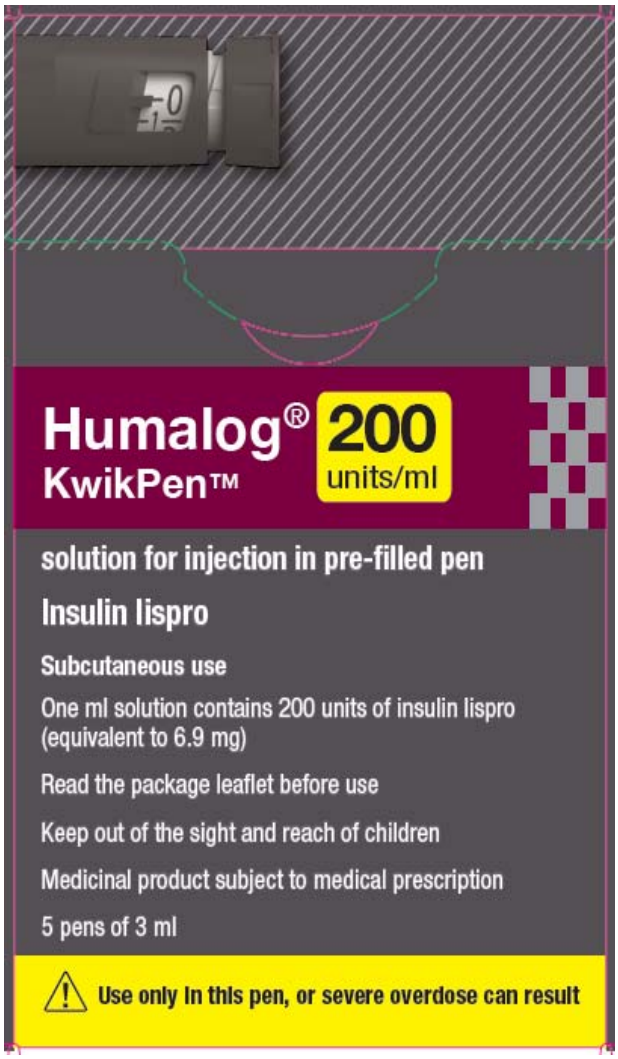
The Humalog 200 units/ml KwikPen carton and pen have been designed to visually differentiate the product from the Humalog 100 units/ml KwikPen. Please advise new patients of the Humalog 200 units/ml design features using the following images.

Key features – Humalog 200 units/ml KwikPen carton

The carton containing the Humalog 200 units/ml KwikPen includes the following design features:

- 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 as for the Humalog 100 units/ml KwikPen.

Humalog 200 units/ml KwikPen outer carton:



Key features – Humalog 200 units/ml Kwikpen pre-filled pen

The Humalog 200 units/ml pre-filled pen contains the following design features:

- The pen colour is dark grey (instead of blue as for the Humalog 100 units/ml KwikPen).
- The label of the pen is burgundy and contains a checkered box (the Humalog 100 units/ml KwikPen label has no checkered box).
- The strength of 200 units/ml is written in a yellow box.

Humalog 200 units/ml KwikPen pre-filled pen:

Call for reporting

Please report any suspected adverse drug reactions, including medication errors or product complaints, to the MHRA through the Yellow Card Scheme:
www.mhra.gov.uk/yellowcard

Alternatively, prepaid Yellow Cards for reporting are available:

- Upon request by mail: FREEPOST YELLOW CARD (no other address details needed)
- By telephoning the Commission on Human Medicines free phone line: 0800 731 6789
- At the back of the British National Formulary
- By electronic download through the Yellow Card section of the MHRA website: www.mhra.gov.uk/yellowcard

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.

Alternatively, to report medication errors, adverse events or product complaints among patients taking Humalog 200 units/ml KwikPen, please contact Lilly at: 01256 315000.

Company contact point

Please refer to the attached SPC for a complete description of risks. Please contact Lilly at: 01256 315000, if you have any questions about the information in this letter or the safe use of Humalog 200 units/ml KwikPen.

Yours faithfully,

Dr Greg Van Wyk
Senior Medical Director – UK/ROI/Northern European Countries
Eli Lilly and Company Limited
enclosures: Patient communication, Humalog 200 units/ml KwikPen SPC