Important Safety Information on the Correct Use of Humalog® (insulin lispro) 200 units/mL KwikPen™ (NEW STRENGTH) to Minimize Medication Errors

2015/09/14

Audience
Healthcare professionals (pharmacists, general practitioners, endocrinologists, nurses, diabetes specialists and diabetes clinics) and patients.

Key messages

- Health Canada has recently authorized Humalog (insulin lispro) KwikPen in a new strength of 200 units/mL.
- Patients should be instructed on the proper use of Humalog (insulin lispro) 200 units/mL KwikPen and reminded of the dose they have been prescribed.
- Patients should be informed that
    - Humalog (insulin lispro) 200 units/mL solution for injection should ONLY be injected using the KwikPen in which it is supplied. Using any other type of device, like a syringe or infusion pump may result in an overdose causing severe low blood sugar.
    - When switching between one concentration of Humalog KwikPen and the other, it is important to understand that the dose-counter window (Dose Knob) on each of the two insulin KwikPen (100 units/mL and 200 units/mL) indicates the number of units of insulin to be injected. As a result the same number of units of insulin would be chosen for both devices. The Kwikpen automatically delivers the correct volume of insulin so conversion of dose between devices is **not** needed.
- Patients with questions or concerns about dosing or administration of Humalog (insulin lispro) 200 units/mL should talk to their healthcare professional.

What is the issue?
Health Canada has recently authorized Humalog (insulin lispro) 200 units/mL KwikPen. Humalog (insulin lispro) 200 units/mL solution for injection should ONLY be administered using the Humalog 200 units/mL KwikPen in which it is supplied. Transfer of the higher concentration insulin lispro 200 units/mL from the Humalog 200 units/mL KwikPen to a different insulin delivery system may lead to overdose and severe low blood sugar.

When switching between one concentration of Humalog KwikPen and the other, it is important to understand that the same number of units of insulin should be chosen for both devices. The Kwikpen automatically delivers the correct volume of insulin so conversion of dose between devices is **not** needed. Dose conversions, which are unnecessary given the device design, will lead to under or over dosing, resulting in severe low or high blood sugar.

Products affected
Humalog® 200 units/mL KwikPen™ (insulin lispro for injection)

Background information
Humalog (insulin lispro) 200 units/mL KwikPen is indicated and reserved for the treatment of patients with diabetes requiring daily doses of more than 20 units of rapid-acting insulin. 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.

Information for consumers
Humalog (insulin lispro) is a rapid acting (mealtime) insulin used to treat diabetes. Humalog solution for injection is now approved in 2 strengths: 100 units/mL (U-100) and 200 units/mL (U-200). Humalog 200 units/mL KwikPen has twice as many insulin units in each mL as Humalog 100 units/mL KwikPen.

- The Humalog contained in the Humalog 200 units/mL KwikPen should ONLY be injected with the KwikPen in which it is supplied. Using any other type of device like a syringe or infusion pump may result in an overdose causing life-threatening low blood sugar.
- Dial your usual dose as instructed by your healthcare professional. For example, if your usual dose of Humalog 100 units/mL is 15 units per meal, then you should still take 15 units per meal with the new Humalog 200 units/mL KwikPen.
- Do NOT share your Humalog KwikPen and cartridges with other people even if the needle has been changed.
- If you have any questions or concerns, talk to your healthcare professional.

When you receive your insulin from the pharmacy, always check the package and the label of the pen for the name, type and concentration of the insulin (see image). Before using Humalog 200 units/mL KwikPen, make sure you read the provided Consumer Information Leaflet and Instructions for Use for detailed information.

Information for health care professionals
When prescribing Humalog KwikPen, please ensure that the correct strength is clearly written on the prescription.

Healthcare professionals should inform their patients NOT to transfer insulin from Humalog (insulin lispro) 200 units/mL KwikPen to any other type of delivery device, like a syringe or an infusion pump, as this carries the risk of overdose.

When switching from one Humalog concentration to another, the dosing unit should not be converted since the dose-counter window on each type of insulin pen displays the number of units of insulin to be injected. Unnecessary dose conversion will lead to under or over dosing, resulting in hyper/hypoglycemia.

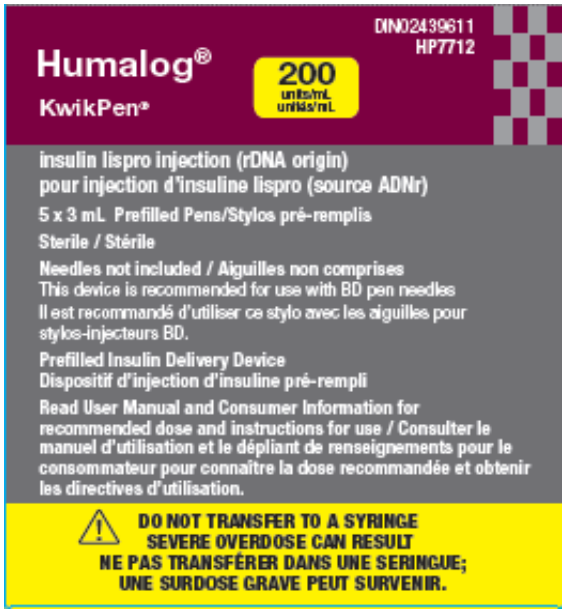
The Humalog 200 units/mL KwikPen carton and pen have been designed to visually differentiate the product from the Humalog 100 units/mL KwikPen. Please advise patients of the following features of the carton and KwikPen:

Humalog 200 units/mL KwikPen carton:

- A yellow warning box containing the wording:

DO NOT TRANSFER TO A SYRINGE
SEVERE OVERDOSE CAN RESULT

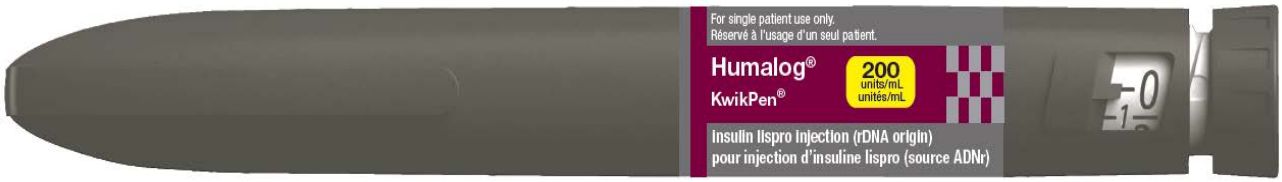
- The concentration of “200 units/mL” is written in a yellow box.
- Background color is dark grey instead of white for the Humalog 100 units/mL KwikPen.



Humalog 200 units/mL KwikPen carton

Humalog 200 units/mL KwikPen pre-filled pen:

- The pen colour is dark grey.
- The dose knob is dark grey with a burgundy ring on the end.
- The label of the pen is burgundy and contains a checkered box.
- The concentration of 200 units/mL is written in a yellow box.



Humalog 200 units/mL KwikPen

Action taken by Health Canada
Health Canada is communicating this important safety information to healthcare professionals and to the public through its MedEffect Canada website.

Report health or safety concerns
Managing marketed health product-related side effects depends on health care professionals reporting them. Any case of serious hyper/hypoglycemia or other serious or unexpected side effects in patients receiving Humalog (insulin lispro) 200 unit/mL KwikPen should be reported to Eli Lilly Canada Inc. or Health Canada at the following address:

Eli Lilly Canada Inc.
Customer Response Centre
Eli Lilly Canada Inc.
3650 Danforth Avenue
Toronto, Ontario M1N 2E8
Tel: 1-888-545-5972 Fax: 1-888-898-2961

To correct your mailing address or fax number, contact Eli Lilly Canada Inc.

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax.

For other health product inquiries related to this communication, please contact Health Canada at:
Marketed Health Products Directorate
E-mail: mhpd_dpsc@hc-sc.gc.ca
Tel: (613) 954-6522
Fax: (613) 952-7738

Sincerely,

Original signed by

Doron Sagman, MD, FRCPC
Vice President, Research & Development
Eli Lilly Canada Inc.

References:

Humalog® 200 units/mL KwikPen® (insulin lispro for injection) Product Monograph, Eli Lilly Canada Inc. April 2, 2015.