

August 2017

IMPORTANT PRESCRIBING INFORMATION

Subject: The dose for Humalog® U-200 KwikPen® (insulin lispro injection 200 units/mL) should **NOT** be changed based on the concentration, and patients should **NOT** transfer insulin from Humalog U-200 KwikPen to an insulin syringe or insulin pump.

Dear Healthcare Professional:

Humalog® U-200 KwikPen® is a rapid-acting human insulin analog indicated to improve glycemic control in adults and children with diabetes mellitus.

Humalog U-200 KwikPen contains insulin lispro 200 units/mL, which is twice the concentration of standard U-100 rapid-acting insulin. Humalog U-200 KwikPen is the same size as other insulin pens, but holds 600 units of insulin lispro. Most other insulin pens hold 300 units of insulin.

Important Information for Prescribers

- You do NOT need to change the patient's prescribed insulin dose based on the concentration of the product.
- The Humalog U-200 KwikPen device was designed to deliver the dose dialed on the pen without the need for dose conversion.

For example, if your patient requires 15 units of U-100 rapid-acting insulin per meal, and you wish to transition your patient to Humalog U-200 KwikPen: The prescription should still be written for 15 insulin units per meal, and the patient would still dial to 15 units on Humalog U-200 KwikPen. The Humalog U-200 KwikPen device was designed so that the unit dose would be delivered in half the volume of what would be delivered by Humalog U-100 KwikPen.

Select Safety Information for Humalog U-200 KwikPen

- Humalog is contraindicated during episodes of hypoglycemia and in patients who are hypersensitive to Humalog or any of its excipients.
- Never share a Humalog KwikPen, cartridge, reusable pen compatible with Lilly 3 mL cartridges, or syringe between patients as it poses a risk for transmission of blood-borne pathogens.
- Instruct patients to always check the insulin label before each injection to avoid medication errors. Do not transfer Humalog U-200 from the Humalog KwikPen to a syringe as overdose and severe hypoglycemia can occur.
- Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with Humalog. If hypersensitivity reactions occur, discontinue Humalog and treat per standard of care until signs and symptoms resolve.

Please see Important Safety Information on page 4 and Full Prescribing Information available at <http://uspl.lilly.com/humalog/humalog.html>.

Humalog 200^{units/mL}
KwikPen®

insulin lispro injection
200 units/mL

Lilly

Important Instructions to Provide to Your Patient

- Humalog U-200 KwikPen is made to deliver the prescribed dose by dialing the pen to the number of units per dose.
- Instruct patients **NOT to transfer** insulin from Humalog U-200 KwikPen to a syringe or insulin pump for administration. The unit markings on insulin syringes will **NOT** measure their dose correctly and they may get too many units of insulin. This may result in a severe overdose and potentially SEVERE hypoglycemia.
- It is critical that you instruct your patients that they should **ALWAYS** have a backup pen, and if there is a problem with the pen, do **NOT transfer** to a syringe. Instead, they should use the backup pen or contact a pharmacist, healthcare provider, or The Lilly Answers Center for more information at 1-800-LillyRx (1-800-545-5979).

Reporting Adverse Events or Product Complaints

To report adverse events or product complaints among patients using Humalog U-200 KwikPen, please contact The Lilly Answers Center at 1-800-LillyRx (1-800-545-5979). Alternatively, adverse event or product complaint information may be reported to the Food and Drug Administration online: <http://www.fda.gov/safety/medwatch/default.htm>.

This letter is not intended as a complete description of the safety considerations associated with the use of Humalog U-200 KwikPen. Please refer to the Full Prescribing Information at <http://uspl.lilly.com/humalog/humalog.html> for a complete description of risks.

Please contact Lilly at 1-800-LillyRx (1-800-545-5979) if you have any questions about the information in this letter or the safe and effective use of Humalog U-200 KwikPen.

Sincerely,

Robert Baker, M.D.
Vice President, Global Patient Safety
Eli Lilly and Company

Please see Important Safety Information on page 4 and Full Prescribing Information available at <http://uspl.lilly.com/humalog/humalog.html>.

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KwikPen®

insulin lispro injection
200 units/mL

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