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Lilly's Humalog® 200 units/mL KwikPen® Now Available in U.S. Pharmacies

First and only concentrated mealtime insulin analog may help people with diabetes fit their treatment into their daily lives

INDIANAPOLIS, Aug. 18, 2015 /PRNewswire/ -- Humalog® 200 units/mL KwikPen® (insulin lispro 200 units/mL; U-200), the first and only concentrated mealtime insulin analog in the U.S., is now available in pharmacies, Eli Lilly and Company (NYSE: LLY) announced today. Humalog U-200 KwikPen is a prefilled pen containing a concentrated formulation of Lilly's rapid-acting insulin Humalog® (insulin lispro 100 units/mL) to improve glycemic control in people with type 1 and type 2 diabetes. It is intended for people who are already taking mealtime insulin.



Humalog U-200 KwikPen holds twice as many units of insulin (600 units vs. 300 units) as the U-100 formulation in the same three-milliliter cartridge volume, offering patients a pen that lasts longer, which facilitates fewer pen changes every month. This may help patients who require higher daily doses of mealtime insulin fit their treatment into their lives.

"This is an important new option for many people with diabetes," said David Kendall, M.D., vice president, Medical Affairs, Lilly Diabetes. "Like everyone else, people with diabetes have busy lives. More rapid-acting insulin in a single pen may help patients worry less about running out when their plans change unexpectedly."

"For nearly 20 years, the Humalog brand has offered people who require mealtime insulin an array of options to meet their needs," Kendall said. "Lilly is pleased to offer another choice to help people with diabetes improve their glycemic control."

The most common side effect of Humalog is hypoglycemia (low blood sugar) that may be severe and cause unconsciousness, seizures and death. Humalog U-200 KwikPen delivers the same dose in half the volume of U-100 mealtime insulin pens, with no dose conversions required, and can be dialed in one-unit increments to a maximum of 60 units per injection.

As with other mealtime insulin pens, Humalog U-200 KwikPen must be used within 28 days after initial use, even if insulin remains. Unused pens should be stored in the refrigerator, but once a pen has been used for the first time, it should be kept at room temperature.

For more information on Humalog U-200 KwikPen, visit <http://Humalog.com/u200>.

Indication: HUMALOG is a rapid-acting human insulin analog indicated to improve glycemic control in adults and children with diabetes mellitus.

Important Safety Information for Humalog 100 units/mL and Humalog 200 units/mL KwikPen

What is the most important information I should know about Humalog?

- Do not share your Humalog KwikPen, cartridges, reusable pen compatible with Lilly 3 mL cartridges, or syringes with other people, even if the needle has been changed. You may give other people a serious infection or get a serious infection from them.
- Humalog 200 units/mL KwikPen contains 2 times as much insulin (200 U/mL) in 1 mL as standard insulin (100 U/mL).
- The Humalog contained in the Humalog U-200 KwikPen should ONLY be injected with the Humalog U-200 KwikPen. Do not withdraw Humalog U-200 from the pen using a syringe. It could result in an overdose causing severe low blood sugar which may put your life in danger.
- Do not change the insulin you use without talking to your healthcare provider. Changes may make you more likely to

experience low or high blood sugar. Changes should be made cautiously under the supervision of your healthcare provider.

- Test your blood sugar levels as your healthcare provider instructs.
- Your insulin dose may need to change because of illness, stress, other medicines you take, change in diet, or change in physical activity or exercise.
- When used in a pump, do not mix or dilute Humalog U-100 with any other insulin or liquid. Do not use Humalog U-200 in an insulin pump.

Who should not take Humalog?

- Do not take Humalog if your blood sugar is too low (hypoglycemia) or if you are allergic to insulin lispro or any of the ingredients in Humalog.

Before using Humalog, what should I tell my healthcare providers?

- About all of your medical conditions, including liver, kidney, or heart failure or other heart problems.
- If you are pregnant, planning to become pregnant, or are breastfeeding.
- About all the medicines you take, including prescription (especially ones commonly called TZDs [thiazolidinediones]) and nonprescription medicines, vitamins, and herbal supplements.

How should I use Humalog?

- Humalog is a rapid-acting insulin. Take Humalog within fifteen minutes before eating or right after eating a meal.
- Always make sure you receive the correct type of Humalog from the pharmacy.
- Do not use Humalog if it is cloudy, colored, or has solid particles or clumps in it.
- Do not mix Humalog U-200 with any other insulin.
- Inject Humalog under your skin (subcutaneously). Never inject into a vein or muscle. Change (rotate) your injection site with each dose. Make sure you inject the correct insulin and dose.
- Do not re-use needles. Always use a new needle for each injection. Re-use of needles can cause you to receive the wrong dose of Humalog and result in infection.
- Do not drive or operate heavy machinery until you know how Humalog affects you. Do not use alcohol while using Humalog.

What are the possible side effects of Humalog?

- Severe low blood sugar can cause unconsciousness (passing out), seizures, and death. Low blood sugar is the most common side effect. There are many causes of low blood sugar, including taking too much Humalog. It is important to treat it quickly. You can treat mild to moderate low blood sugar by drinking or eating a quick source of sugar right away. Symptoms may be different for each person. Be sure to talk to your healthcare provider about low blood sugar symptoms and treatment.
- Severe life-threatening allergic reactions (whole-body reactions) can happen. Get medical help right away if you develop a rash over your whole body, have trouble breathing, have a fast heartbeat, or are sweating.
- Humalog can cause life-threatening low potassium in your blood (hypokalemia), which can cause severe breathing problems, irregular heartbeat, and death.
- Serious side effects can include swelling of your hands and feet and heart failure when taking certain pills called thiazolidinediones or "TZDs" with Humalog. This may occur in some people even if they have not had heart problems before. Tell your healthcare provider if you have shortness of breath, swelling of your ankles or feet, or sudden weight gain, which may be symptoms of heart failure. Your healthcare provider may need to adjust or stop your treatment with TZDs or Humalog.
- Failure of your insulin pump or infusion set or degradation of the insulin in the pump can cause hyperglycemia and ketoacidosis. Always carry an alternate form of insulin administration in case of pump failure. The most common side effects of Humalog include low blood sugar, allergic reactions, including reactions at your injection site, skin thickening or pits at the injection site (lipodystrophy), itching, and rash. These are not all of the possible side effects. Ask your healthcare provider for more information or for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Humalog is available by prescription only.

For additional information, talk to your healthcare providers and please click to access [Full Prescribing Information](#) and [Patient Prescribing Information](#).

Please see Instructions for Use included with the pen.

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About Diabetes

Approximately 29 million Americans have type 1 and type 2 diabetes.¹ Type 2 diabetes is the most common type, accounting for an estimated 90 to 95 percent of all diabetes cases.¹ Diabetes is a chronic disease that occurs when the body either does not properly produce or use the hormone insulin.¹

About Lilly Diabetes

Lilly has been a global leader in diabetes care since 1923, when we introduced the world's first commercial insulin. Today we are building upon this heritage by working to meet the diverse needs of people with diabetes and those who care for them. Through research and collaboration, a broad and growing product portfolio and a continued determination to provide real solutions—from medicines to support programs and more—we strive to make life better for all those affected by diabetes around the world. For more information, visit www.lillydiabetes.com and follow @LillyDiabetes on Twitter.

About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and newsroom.lilly.com/social-channels.

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This press release contains forward-looking statements about Humalog 200 units/mL KwikPen for use in the treatment of diabetes. It reflects Lilly's current beliefs; however, as with any such undertaking, there are substantial risks and uncertainties in the process of drug development and commercialization. There is no guarantee that future study results and patient experience will be consistent with study findings to date or that Humalog 200 units/mL KwikPen will be commercially successful. For further discussion of these and other risks and uncertainties, please see Lilly's latest Forms 10-Q and 10-K filed with the U.S. Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

¹ Centers for Disease Control and Prevention. National Diabetes Statistics Report: *Estimates of Diabetes and Its Burden in the United States*, 2014. Atlanta, GA: U.S. Department of Health and Human Services; 2014.

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The logo for Humalog 200 U/mL KwikPen. The word "Humalog" is written in a large, stylized, purple cursive font. To its right, "200" is written in a bold, purple sans-serif font, followed by "U/mL" in a smaller, purple sans-serif font. Below "Humalog" and "200" is the word "KwikPen" in a bold, brown sans-serif font. A registered trademark symbol (®) is located to the left of "KwikPen".

insulin lispro injection (rDNA origin)
200 units/mL

Lilly

Photo - <http://photos.prnewswire.com/prnh/20150817/258888>

Logo - <http://photos.prnewswire.com/prnh/20150817/258887LOGO>

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To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/lillys-humalog-200-unitsml-kwikpen-now-available-in-us-pharmacies-300129849.html>

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