



Humalog® Junior KwikPen® Now Available in the U.S. for People with Diabetes

October 4, 2017

Humalog Junior KwikPen combines the convenience of a prefilled pen with the ability to dose in half-unit increments

INDIANAPOLIS, Oct. 4, 2017 /PRNewswire/ -- Humalog® Junior KwikPen® [insulin lispro injection 100 units/mL] is now available by prescription for the treatment of diabetes in the U.S. This innovation is the latest in the treatment and delivery options Eli Lilly and Company (NYSE: LLY) offers for people with type 1 or type 2 diabetes. Humalog Junior KwikPen is the only prefilled, disposable half-unit insulin pen.

In June 2017, the U.S. Food and Drug Administration (FDA) approved Humalog Junior KwikPen for the treatment of diabetes. In September 2017, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion for Humalog Junior KwikPen in the European Union and is pending final approval, expected later this year.

"Learning how to inject insulin can be overwhelming, especially for newly diagnosed children and their caregivers. People often feel shock and anxiety, and may struggle with the reality of fitting diabetes into daily life," said Sherry Martin, M.D., vice president, Global Medical Affairs, Lilly Diabetes. "We hope to help take away some of the worries about the injection process with Humalog Junior KwikPen. Because it is prefilled, there are fewer steps for people to learn, and the half-unit increments make dosing more precise."

Humalog Junior KwikPen, which is lighter and shorter than other half-unit insulin pens, provides an option for people who prefer a prefilled pen and need the precision of half-unit dosing, such as those with insulin sensitivity and some older adults for whom rounding to the nearest whole-unit dose is not adequate.

Until now, the only way to deliver half units of insulin with a pen was through a reusable pen, which requires users to remove and load cartridges. Humalog Junior KwikPen offers fine-tuned dosing in a convenient prefilled disposable pen.

Humalog Junior KwikPen enables finer dose adjustment (0.5 vs 1 unit dose increments) for people who take relatively small doses (≤ 30 units at mealtimes) of Humalog® U-100 (insulin lispro injection 100 units/mL). The design of Humalog KwikPen meets or exceeds the requirements and standards for needle-based injections set by the International Organization for Standardization.

For more information about Humalog Junior KwikPen, the support resources, please visit www.Humalog.com.

Important Safety Information for Humalog

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

- **Do not share your Humalog Junior KwikPen 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.**
- 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.

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.
- 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.
- 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 see accompanying [Full Prescribing Information](#) and [Patient Prescribing Information](#).

Please see Instructions for Use included with the Humalog Junior KwikPen.

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About Diabetes

Approximately 29 million Americans¹ and an estimated 415 million people worldwide have type 1 and type 2 diabetes.² 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 does not either properly produce or use the hormone insulin.

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 wide range of therapies 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 or follow us on Twitter: [@LillyDiabetes](https://twitter.com/LillyDiabetes) and Facebook: [LillyDiabetesUS](https://www.facebook.com/LillyDiabetesUS).

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 www.lilly.com/newsroom/social-channels.

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This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Humalog Junior KwikPen and Lilly's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that future study results will be consistent with study findings to date, that Humalog Junior KwikPen will receive additional regulatory approvals or that Humalog Junior KwikPen will prove to be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect

events after the date of this release.

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References

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2. International Diabetes Federation. IDF Diabetes Atlas, 7th edn. Brussels, Belgium: International Diabetes Federation, 2015. <http://www.idf.org/diabetesatlas>.

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