U.S. FDA Approves Humalog® Junior KwikPen® for the Treatment of Diabetes

June 13, 2017

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INDIANAPOLIS, June 13, 2017 – The U.S. Food and Drug Administration (FDA) approved Eli Lilly and Company's (NYSE: LLY) Humalog ® Junior KwikPen® for the treatment of diabetes. Humalog Junior KwikPen is a prefilled pen with half-unit dosing capability, enabling finer dose adjustment for those who need it.

"We are pleased to be able to meet the needs of people who prefer a prefilled insulin pen but require the fine-tuning that half-unit dosing provides. The prefilled Humalog Junior KwikPen can help make insulin injections easier to incorporate into their everyday lives," said Sherry Martin, M.D., vice president, Global Medical Affairs, Lilly Diabetes. "This latest approval speaks to Lilly Diabetes' commitment to making lives of people affected by diabetes better."

The Humalog Junior KwikPen design meets or exceeds the requirements and standards for needle-based injections set by the International Organization for Standardization.

Humalog Junior KwikPen will be available in U.S. pharmacies later this year. Lilly also has a pending application for Humalog Junior KwikPen regulatory approval in the European Union.

Important Safety Information for Humalog

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.**
- 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 with any other insulin or liquid.

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.
- 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.
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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[1] 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 and Facebook: 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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[1] Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2014. Available at: http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf. October 2014

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

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