



FDA approves Lyumjev™ (insulin lispro-aabc injection), Lilly's new rapid-acting insulin

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INDIANAPOLIS, June 15, 2020 /PRNewswire/ -- The U.S. Food and Drug Administration (FDA) has approved Lyumjev™ (insulin lispro-aabc injection, 100 units/mL and 200 units/mL), Eli Lilly and Company's (NYSE: LLY) new rapid-acting insulin indicated to improve glycemic control in adults with type 1 and type 2 diabetes. Lyumjev is a novel formulation of insulin lispro, developed to speed the absorption of insulin into the blood stream and reduce A1C levels. As a rapid-acting mealtime insulin, Lyumjev controls high blood sugar levels after meals in adults with diabetes, similar to how natural insulin works after meals in people without diabetes.

Experience the interactive Multichannel News Release here: <https://www.multivu.com/players/English/8733851-eli-lilly-and-company-lyumjev-fda-approval/>

"Thanks to advances in glucose monitoring, the people with diabetes I treat in my practice are able to more clearly see the blood glucose spikes that happen naturally after a meal," said Mark Warren, M.D., Assistant Professor of Medicine, Campbell University of Osteopathic Medicine. "With its fast onset, Lyumjev is a meaningful development for people who want their insulin to help manage their A1C and reduce those post-meal spikes."

The approval of Lyumjev was based on data from the Phase 3 studies PRONTO-T1D and PRONTO-T2D, which were randomized, active controlled, treat-to-target comparisons of Lyumjev and Humalog® (insulin lispro injection, 100 units/mL) in adults with type 1 and type 2 diabetes, respectively. Both studies met the primary endpoint of noninferior A1C reduction from baseline compared to Humalog at 26 weeks, when Lyumjev and Humalog were dosed at mealtime. Key endpoints were adjusted for multiple testing, including the comparisons of one- and two-hour postprandial glucose. In both studies, Lyumjev demonstrated superior reduction in blood glucose spikes at both one hour and two hours after a test meal compared to Humalog.

In Phase 3 studies, Lyumjev and Humalog had similar safety and tolerability profiles. Lyumjev is contraindicated during episodes of hypoglycemia and in patients with hypersensitivity to insulin lispro or one of the excipients in Lyumjev. Hypoglycemia, which can be serious and life-threatening, is the most common adverse reaction associated with insulins, including Lyumjev.

"We are proud to build on our long heritage of developing new insulins with the approval of Lyumjev, an important new treatment option to help control post-meal blood sugar levels," said Leonard Glass, M.D., F.A.C.E., vice president of Medical Affairs, Lilly. "Keeping blood sugar in the target range following meals can be challenging for people living with diabetes, and the approval of Lyumjev underscores our commitment to meeting their needs."

Lyumjev will be included in the Lilly Insulin Value Program, allowing anyone with commercial insurance and those without insurance at all to fill their monthly prescription of Lyumjev for \$35. When Lyumjev is available in U.S. pharmacies, this savings option can be obtained by calling the Lilly Diabetes Solution Center at (833) 808-1234, Monday through Friday from 8 a.m. to 8 p.m. (ET). The list price of Lyumjev will be the same as the list price for Humalog. Lilly is in discussions with insurance providers to make Lyumjev available to as many people as possible.

"Lilly is committed to ensuring all of our insulins, including Lyumjev, are accessible to people living with diabetes through our wide range of affordability options, such as the Lilly Insulin Value Program," said Adrienne Brown, vice president, U.S. Connected Care and Insulins, Lilly. "We want people who use Lilly insulin and need help affording their medicine to know that we're here to support them."

Lyumjev has been approved by regulatory authorities in several global markets, including Japan and the European Union in March 2020. Lilly is currently working to make Lyumjev available to adults with diabetes in the U.S. as quickly as possible.

Patients and healthcare providers with questions about Lyumjev can visit <http://www.Lyumjev.com> or call The Lilly Answers Center at 1-800-LillyRx (1-800-545-5979), Monday through Friday from 9 a.m. to 8 p.m. ET.

Terms, conditions, and limitations apply to savings cards. Not available to those patients with government insurance such as Medicaid, Medicare, Medicare Part D, TRICARE®/CHAMPUS, Medigap, DoD, or any State Patient or Pharmaceutical Assistance Program.

About the Lyumjev clinical studies

PRONTO-T1D and PRONTO-T2D were randomized, active controlled, treat-to-target comparisons of Lyumjev (insulin lispro-aabc injection, 100 units/mL) and Humalog (insulin lispro injection, 100 units/mL), both in combination with either insulin glargine or insulin degludec in adults with type 1 and type 2 diabetes, respectively. The studies were designed as treat-to-target trials in which each arm was treated to achieve the same level of blood glucose control and evaluated other important treatment effects, such as rates of hypoglycemia and post-meal glucose control. A subset of patients randomized to PRONTO-T1D participated in an evaluation of 24-hour ambulatory glucose profiles captured with blinded continuous glucose monitoring (CGM) over a two-week period. Both studies met the primary endpoint of noninferior A1C reduction from baseline compared to Humalog at 26 weeks, when Lyumjev and Humalog were dosed at mealtime. Key endpoints were adjusted for multiple testing, including the comparisons of one- and two-hour postprandial glucose. In both studies, Lyumjev demonstrated superior reduction in blood glucose spikes at both one hour and two hours after a test meal compared to Humalog. Additionally, in studies evaluating the time action profile of this new insulin, Lyumjev appeared in the blood stream approximately one minute after injection.

PURPOSE and SAFETY SUMMARY

Important Facts About LYUMJEV™ (LOOM-jehv) and Humalog® (HU-ma-log)

- Lyumjev is also known as insulin lispro-aabc injection. Humalog is also known as insulin lispro injection.
- Lyumjev is a fast-acting insulin. Lyumjev is used to control high blood sugar in adults with diabetes. Humalog is a fast-acting insulin. Humalog is used to control high blood sugar in adults and children with diabetes. Lyumjev and Humalog are available only with a prescription.
- Lyumjev comes in two strengths: U-100 (100 units per milliliter) and U-200 (200 units per milliliter). The Lyumjev U-200 prefilled pen contains **2 times as much insulin** per 1 milliliter as standard (U-100) insulin. Humalog U-100 contains 100 units of insulin per milliliter. The dose window of the pen shows the number of insulin units to be delivered.
- It is not known if Lyumjev is safe and effective for children. It is not known if Humalog is safe and effective for children with type 2 diabetes or for children younger than 3 years of age with type 1 diabetes as there were no studies done with Humalog in these groups of children. If your doctor decides to give your child any insulin products, he or she may give you special instructions.

All Lyumjev and Humalog products contain insulin lispro.

Warnings

Do not take Lyumjev or Humalog if you have:

- symptoms of low blood sugar (hypoglycemia)
- an allergy to Lyumjev or Humalog or any of their ingredients.

Do not reuse needles or share your insulin injection supplies with other people. This includes your:

- prefilled pen for use by a single patient
- cartridges
- reusable pen that works with Lilly 3mL cartridges available for Humalog
- needles
- syringes

You or the other person can get a serious infection. This can happen even if you change the needle.

Do not change the type of insulin you take or your dose, unless your doctor tells you to. This could cause low or high blood sugar, which could be serious.

Do not use a syringe to remove Lyumjev or Humalog from your prefilled pen. This can cause you to take too much insulin. Taking too much insulin can lead to severe low blood sugar. This may result in seizures or death.

Lyumjev and Humalog may cause serious side effects. Some of these can lead to death. The possible serious side effects are:

- **Low blood sugar.** This can cause:
 - dizziness or lightheadedness
 - headache
 - shakiness
 - irritability
 - sweating
 - blurred vision
 - fast heartbeat
 - mood change
 - confusion
 - slurred speech
 - anxiety
 - hunger

If you are at risk of having severely low blood sugar, your doctor may prescribe a glucagon emergency kit. These are used when your blood sugar becomes too low and you are unable to take sugar by mouth. Glucagon helps your body release sugar into your bloodstream.

- **Severe allergic reaction.**

Get emergency help right away if you have:

- a rash over your whole body
- sweating
- extreme drowsiness
- swelling of your face, tongue, or throat
- trouble breathing
- a faint feeling
- dizziness
- a fast heartbeat
- shortness of breath
- confusion

- **Low potassium in your blood.** This can lead to severe breathing problems, irregular heartbeat, and death.

- **Heart failure.** Taking diabetes pills called thiazolidinediones (thIE-uh-zOH-li-dEEEn-dIE-OHns), or "TZDs," with Lyumjev or Humalog may cause heart failure in some people. This includes people who do not have any heart problems. If you have heart failure, it may get worse if you take TZDs with Lyumjev or Humalog. Tell your doctor if you have any new symptoms of heart failure, or if they get worse. Some symptoms of heart failure include: shortness of breath, swelling of ankles and feet, and sudden weight gain. Your doctor may need to change or stop treatment with TZDs and your insulin lispro product.

- **High blood sugar and ketoacidosis for Humalog insulin pump users.** You can have these serious problems when your

insulin pump or infusion set stops working. They can also happen if your insulin is no longer effective. For these reasons, always keep extra insulin injection supplies with you.

Common side effects

The most common side effects of **Lyumjev and Humalog** are:

- low blood sugar
- reactions where you have injected insulin
- itching
- weight gain
- allergic reactions
- skin thickening or pits at the injection site
- rash

Other most common side effects with Humalog include swelling of your hands or feet.

These are not all of the possible side effects. Tell your doctor if you have any side effects. You can report side effects at 1-800-FDA-1088 or www.fda.gov/medwatch.

Before using

Talk with your doctor about low blood sugar and how to manage it. Also tell your doctor:

- about all of the medicines you take, including over-the-counter medicines, vitamins, and herbal supplements.
- about any other prescription medicines you take, especially ones called TZDs.
- about all of your medical conditions, including if you have heart failure or other heart, liver, or kidney problems.
- if you are pregnant, breastfeeding, or plan to become pregnant or breastfeed.

How to take

Read the **Instructions for Use** that come with your **Lyumjev or Humalog**. Be sure to take your **Lyumjev or Humalog** and **check your blood sugar levels** exactly as your doctor tells you to. Your doctor may tell you to change your dose because of illness, increased stress, or changes in your weight, diet, or physical activity level. He or she may also tell you to change the amount or time of your dose because of other medicines or different types of insulin you take.

Before injecting your Lyumjev or Humalog

You can inject your insulin dose yourself, or you can have a trained caregiver inject it for you. Make sure you or your caregiver:

- Check the insulin label before each injection. This will help you make sure that you are taking the correct insulin.
- Use a new needle for each injection. You can get a serious infection or the wrong dose of insulin if you re-use needles.
- Change (rotate) where you inject your insulin with each dose. This can reduce your chance of getting pits, lumps, or thickened skin where you inject your insulin. **Do not** inject your insulin into the exact same spot or where the skin has pits or lumps. **Avoid** injecting into thickened, tender, bruised, scaly, hard, scarred, or damaged skin.

When you are ready to inject

- Inject Lyumjev under your skin at the beginning of a meal or within 20 minutes after you start eating a meal.
- Inject Humalog under your skin within 15 minutes before or right after you eat a meal.

Staying safe while taking your Lyumjev or Humalog

To stay safe while taking your insulin, be sure to **never** inject Lyumjev U-200 in your vein, muscle, or with an insulin pump. Also be sure **not to**:

- mix Lyumjev with other insulins
- drive or use heavy machinery until you know how your Lyumjev or Humalog affects you.
- drink alcohol or use other medicines that contain alcohol when taking your Lyumjev or Humalog.

Learn more

For more information, call 1-800-545-5979 or go to www.Lyumjev.com or www.humalog.com

This summary provides basic information about Lyumjev and Humalog. It does not include all information known about these medicines. Read the information that comes with your prescription each time your prescription is filled. This information does not take the place of talking with your doctor. Be sure to talk to your doctor or other health care provider about your insulin lispro product and how to take it. Your doctor is the best person to help you decide if these medicines are right for you.

Please see Lyumjev [Full Prescribing Information](#) including [Patient Prescribing Information](#)
Please see Humalog [Full Prescribing Information](#) including [Patient Prescribing Information](#)

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About Diabetes

Approximately 34 million Americans¹ (just over 1 in 10) and an estimated 463 million adults worldwide² have diabetes. Type 2 diabetes is the most common type internationally, accounting for an estimated 90 to 95 percent of all diabetes cases in the United States alone¹. Diabetes is a chronic disease that occurs when the body does not 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, collaboration and quality manufacturing we strive to make life better for people affected by diabetes and related conditions. We work to deliver breakthrough outcomes through innovative solutions—from medicines and technologies to support programs and more. For the latest updates, visit <http://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 health care leader that unites caring with discovery to create medicines that 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 lilly.com and lilly.com/newsroom. P-LLY

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Lyumjev™ (insulin lispro-aabc injection) as a treatment to improve glycemic control in adults with type 1 and type 2 diabetes, and reflects Lilly's current beliefs. However, as with any pharmaceutical product or medical device, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there is no guarantee that the U.S. Food and Drug Administration approval ensures that Lyumjev will be commercially successful, or that the company will meet its anticipated timelines for the roll out of this medicine. 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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