



Lilly expands insulin affordability options with lower-priced versions of Humalog® Mix75/25™ KwikPen® and Humalog® Junior KwikPen®

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List price will be 50 percent less than branded versions

INDIANAPOLIS, Jan. 14, 2020 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced plans to add two more cost-saving options to its suite of solutions for people who use Lilly insulin by introducing lower-priced versions of Humalog® Mix75/25™ KwikPen® (insulin lispro protamine and insulin lispro injectable suspension 100 units/mL) and Humalog® Junior KwikPen® (insulin lispro injection 100 units/mL). Both insulins will have 50 percent lower list prices compared to the branded versions and will be available by mid-April.

Lilly's first lower-priced insulin, Insulin Lispro Injection (100 units/mL), was made available in May 2019 at a 50 percent lower list price than Humalog® (insulin lispro injection 100 units/mL). In November 2019, more than 67,000 people filled prescriptions for Insulin Lispro Injection, and approximately 10 percent of people using Humalog have transitioned to the lower-priced option. Insulin Lispro Injection is now distributed by all major U.S. wholesalers and can be ordered by any pharmacy. Lilly will begin negotiations immediately with wholesalers and payers to make these additional lower-priced insulins available.

"Lilly is committed to offering the broadest suite of solutions for people who need help affording their insulin, and our lower-priced insulins are important options," said Mike Mason, president, Lilly Diabetes. "But real change to our reimbursement system is needed. Insurance coverage should ensure no one with diabetes is forced to ration or skip doses for financial reasons."

Combined, Humalog U-100, Humalog Mix75/25, and Humalog Junior KwikPen make up more than 90 percent of prescriptions written for a Lilly mealtime insulin. With a lower-priced version of each available, the vast majority of people using a Humalog formulation will have an option that may reduce their out-of-pocket costs. Humalog Mix75/25 is one of Lilly's most prescribed insulins, with nearly 600,000 prescriptions filled in the last 12 months.

These insulins are identical molecules to the branded versions and may be substituted at the pharmacy counter. Because most insurance plans provide affordable copays for chronic medicines that are much lower than the list price, people should ask their pharmacist whether these options reduce their out-of-pocket cost.

"The cost of insulin at the pharmacy varies dramatically depending on a person's insurance coverage," said Mason. "These lower-priced insulins may reduce out-of-pocket costs, especially for people in the coverage gap of Medicare Part D, the uninsured or those with high-deductible insurance plans."

The lower-priced version of Humalog Mix75/25 will be known as Insulin Lispro Protamine and Insulin Lispro Injectable Suspension Mix75/25™ KwikPen® (100 units/mL). The lower-priced version of Humalog Junior KwikPen will be known as Insulin Lispro Injection Junior KwikPen® (100 units/mL). Both will have a list price of \$265.20 for a package of five KwikPens.

More than 95 percent of people using Humalog pay less than \$100 for their monthly prescription at retail pharmacies because of their insurance coverage or one of Lilly's affordability solutions. Anyone who uses a Lilly insulin can call the Lilly Diabetes Solution Center at (833) 808-1234 (9 am to 8 pm EST Monday through Friday) to see whether there is an option that reduces their out-of-pocket costs. Staffed by health care professionals, the Solution Center may provide significant savings on Lilly insulins in multiple ways, including out-of-pocket caps on what people with commercial plans pay at the pharmacy and information about how to access donated Lilly insulin at more than 150 free clinics across the country. In 2019, Lilly's solutions helped up to 20,000 people with diabetes each month reduce their out-of-pocket costs for insulin.

PURPOSE and SAFETY SUMMARY

Important Facts About Humalog® (HU-ma-log) and Insulin Lispro Injection

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

Important Facts about Humalog® Mix50/50™, Humalog® Mix75/25™, and Insulin Lispro Protamine and Insulin Lispro Injectible Suspension Mix75/25

- Humalog Mix50/50 and Humalog Mix75/25 are known as insulin lispro protamine and insulin lispro injectible suspension.
- Humalog Mix50/50, Humalog Mix75/25, and Insulin Lispro Protamine and Insulin Lispro Injectible Suspension Mix75/25 are mixed insulins. This means they contain a mix of fast-acting and intermediate-acting insulins. They are used to control high blood sugar in people with diabetes. They are available only with a prescription.
- It is not known if Humalog Mix50/50, Humalog Mix75/25, or Insulin Lispro Protamine and Insulin Lispro Injectible Suspension Mix75/25 are safe and effective for children younger than 18 years of age. There were no studies done with these insulins in children younger than 18. If your doctor decides to give your child one of these insulins, he or she may give you special instructions.

All Humalog and Insulin Lispro Injection products contain insulin lispro. Humalog Mix50/50, Humalog Mix75/25, and Insulin Lispro Protamine and Insulin Lispro Injectible Suspension Mix75/25 contain insulin lispro protamine mixed with insulin lispro.

Warnings

Do not take Humalog, Insulin Lispro Injection, Humalog Mix50/50, Humalog Mix75/25, or Insulin Lispro Protamine and Insulin Lispro Injectible Suspension Mix75/25 if you have:

- symptoms of low blood sugar (hypoglycemia)
- an allergy to insulin lispro products 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
- 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 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.

Humalog, Insulin Lispro Injection, Humalog Mix50/50, Humalog Mix75/25, and Insulin Lispro Protamine and Insulin Lispro Injectible Suspension Mix75/25 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 light-headedness
 - 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 insulin lispro products 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 these insulin lispro products. 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.** 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 **Humalog, Insulin Lispro Injection, Humalog Mix50/50, Humalog Mix75/25, and Insulin Lispro Protamine and Insulin Lispro Injectible Suspension Mix75/25** are:

- low blood sugar
- reactions where you have injected insulin
- swelling of your hands or feet
- itching
- allergic reactions
- changes in fat tissue where you have injected insulin
- weight gain
- rash

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 **Humalog, Insulin Lispro Injection, Humalog Mix50/50, Humalog Mix75/25, or Insulin Lispro Protamine and Insulin Lispro Injectible Suspension Mix75/25**. Be sure to take your insulin lispro product 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 insulin lispro product

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

- If you are taking Humalog or Insulin Lispro Injection, inject it under your skin within 15 minutes before or right after you eat a meal.
- If you are taking Humalog Mix50/50, Humalog Mix75/25, or Insulin Lispro Protamine and Insulin Lispro Injectible Suspension Mix75/25, inject it under your skin within 15 minutes before you eat a meal.

Staying safe while taking your insulin lispro product

To stay safe while taking your insulin, be sure to **never** inject Humalog U-200, Humalog Mix50/50, Humalog Mix75/25, or Insulin Lispro Protamine and Insulin Lispro Injectible Suspension Mix75/25 in your vein, muscle, or with an insulin pump. Also be sure **not to**:

- mix Humalog U-200, Humalog Mix50/50, Humalog Mix75/25, or Insulin Lispro Protamine and Insulin Lispro Injectible Suspension Mix75/25 with other insulins or liquids.
- drive or use heavy machinery until you know how your insulin lispro product affects you.
- drink alcohol or use other medicines that contain alcohol when taking your insulin lispro product.

Learn more

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

For additional information talk to your doctor and please see Humalog [Full Prescribing Information](#), Insulin Lispro Injection [Full Prescribing Information](#), Humalog Mix75/25 [Full Prescribing Information](#), Insulin Lispro Protamine and Insulin Lispro Injectible Suspension Mix75/25 [Full Prescribing Information](#) and Humalog Mix50/50 [Full Prescribing Information](#).

Please see Patient Information and Instructions for Use included with the product.

This summary provides basic information about Humalog, Insulin Lispro Injection, Humalog Mix50/50, Humalog Mix75/25, and Insulin Lispro Protamine and Insulin Lispro Injectible Suspension Mix75/25. 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.

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About Diabetes

Approximately 30 million Americans¹ and an estimated 425 million adults worldwide have diabetes.² 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 alone.¹ 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. We offer a wide range of therapies and a continued determination to provide real 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 Humalog[®] Mix75/25[™] (insulin lispro protamine and insulin lispro injectable suspension 100 units/mL) or Humalog[®] Junior KwikPen[®] (insulin lispro injection 100 units/mL) as a treatment for patients with diabetes and reflects Lilly's current belief. 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 Humalog[®] Mix75/25[™] (insulin lispro protamine and insulin lispro injectable suspension 100 units/mL) or Humalog[®] Junior KwikPen[®] (insulin lispro injection 100 units/mL) will 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.

1. Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2017. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Dept of Health and Human Services; 2017.

2. International Diabetes Federation. *IDF Diabetes Atlas*, 8th edn. Brussels, Belgium: International Diabetes Federation, 2017. <http://www.diabetesatlas.org>.

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