

Lilly again reduces list price of Insulin Lispro Injection as latest change to affordability options

September 28, 2021

Lilly's Insulin Lispro Injection, 100 units/mL -- first introduced at half the list price of branded Humalog® (insulin lispro injection, 100 units/mL) in 2019 -- will now have a 70 percent lower list price than Humalog U-100 starting January 1, 2022 Insulin Lispro Injection can be ordered through all U.S. retail pharmacies

Monthly prescriptions for all Lilly insulins -- including Insulin Lispro Injection -- remain available for \$35 through the Lilly Insulin Value Program and the Medicare Part D Senior Savings Model

INDIANAPOLIS, Sept. 28, 2021 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) will lower the list price of Insulin Lispro Injection in the U.S. by an additional 40 percent effective January 1, 2022, effectively bringing the list price down to 2008 levels. The new list price will apply to all Lilly's non-branded insulins, including Insulin Lispro Injection, a lower list-priced alternative to Humalog U-100.

The new lower list price is the latest among numerous options that can reduce out-of-pocket costs for Lilly insulin at U.S. retail pharmacies. People using any Lilly insulin – including Insulin Lispro Injection – can fill their monthly prescription for \$35 through the Lilly Insulin Value Program for people with commercial insurance or who are uninsured, and the Senior Savings Model for seniors in participating Medicare Part D plans.

The new list price for Insulin Lispro Injection will be \$82.41 for individual vials and \$159.12 for a pack of five pens – which is 70 percent less than Lilly's branded Humalog U-100 counterparts and can help people who have not activated one of Lilly's affordability solutions.

"Lilly has introduced numerous affordability programs since 2017. Collectively, these solutions are significantly lowering the out-of-pocket costs for people using our insulins," said David A. Ricks, Lilly's chairman and CEO. "Today's list price cut can further help people who are exposed within our healthcare system – the underinsured and uninsured. Half list-priced Insulin Lispro Injection has been adopted by a third of Humalog U-100 consumers. We hope this additional 40 percent cut can expand affordable insulin to more people with diabetes."

Lilly's numerous affordability solutions, combined with insurance coverage, have lowered the average monthly out-of-pocket cost for a prescription of Lilly insulin (regardless of the number of vials or pens) to \$28.05, a 27 percent decrease over the past four years. In addition to lowering the list price of Insulin Lispro Injection, Lilly will keep other affordability programs in place for people using Lilly insulins – including the \$35 co-pay card for the uninsured and people with commercial insurance, and the Senior Savings Model for people in participating Medicare Part D plans.

Insulin Lispro Injection Access

All major wholesalers stock and deliver Insulin Lispro Injection to U.S. pharmacies, and payers will continue to have the opportunity to make the lower list-priced insulins available to people living with diabetes. Pharmacists can substitute Insulin Lispro Injection U-100 for Humalog U-100 without a new prescription because they are the same insulin. Any retail pharmacy that does not stock Insulin Lispro Injection can obtain it from a wholesaler in 1-2 days.

Approximately 1 in 3 prescriptions for Lilly's U-100 mealtime insulin - Lilly's most commonly used insulin formulation - is for Insulin Lispro Injection.

The greatest benefit will be seen by people who face higher out-of-pocket costs – such as people without insurance and those with high deductible plans or co-insurance. Most people using Insulin Lispro Injection are unlikely to see a change in what they pay for their monthly prescription because they have fixed insurance co-pays or already use one of Lilly's affordability programs. Therefore, people should continue to refill insulin prescriptions at their normal pace. Given that out-of-pocket costs at the pharmacy can vary greatly due to insurance plan designs and co-pays, people should ask their pharmacist whether these lower list-priced options reduce their out-of-pocket costs.

"The affordability options we have introduced in recent years have helped many people who were struggling to afford their insulin," said Mike Mason, president, Lilly Diabetes. "Regardless of their circumstances, people who cannot afford their Lilly insulin should call the Lilly Diabetes Solution Center, or go to insulinaffordability.com, to find solutions to help them lower their out-of-pocket costs."

People who pay more than \$35 a month for their prescription of Lilly insulin can lower their out-of-pocket costs by visiting insulinaffordability.com or by calling the Lilly Diabetes Solution Center at (833) 808-1234.

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 Injectable Suspension Mix75/25

- Humalog Mix50/50 and Humalog Mix75/25 are known as insulin lispro protamine and insulin lispro injectable suspension.
- Humalog Mix50/50, Humalog Mix75/25, and Insulin Lispro Protamine and Insulin Lispro Injectable Suspension Mix75/25 are mixed U-100 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 Injectable 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 Injectable 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 Injectable 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 Injectable 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
 sweating
 confusion
- headache
 blurred vision slurred speech
 - shakiness fast heartbeat• anxiety
- irritability
 mood change 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• trouble breathing• a fast heartbeat
- sweating
- a faint feeling
 shortness of breath
- extreme drowsiness
- dizziness confusion
- swelling of your face, tongue, or throat
 - 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-dEEn-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 Injectable Suspension Mix75/25 are:

- low blood sugar
- allergic reactions
 changes in fat tissue where you have injected insulin
- reactions where you have injected insulin
- swelling of your hands or feetitching
- weight gainrash

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 Injectable 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 Injectable 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 Injectable 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 Injectable 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.

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

Humalog[®], Humalog[®] Mix50/50 [™], and Humalog[®] Mix75/25 [™]are trademarks and registered trademarks owned or licensed by Eli Lilly and Company, its subsidiaries, or affiliates.

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For additional information, talk to your healthcare providers and please click to access Humalog <u>Full Prescribing Information</u> and <u>Patient Information</u>, Humalog Mix75/25 <u>Full Prescribing Information</u> and <u>Patient Information</u>, Humalog Mix75/25 <u>Full Prescribing Information</u> and <u>Patient Information</u>, Humalog Mix75/25 <u>Full Prescribing Information</u> and <u>Patient Information</u>, Insulin Lispro Injection <u>Full Prescribing Information</u> and <u>Patient Information</u>, Insulin Lispro Protamine and Insulin Lispro Injectable Suspension Mix75/25 <u>Full Prescribing Information</u> and <u>Patient Information</u>, Insulin

Please see Instructions for Use included with the product.

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 alone.² 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, visi<u>http://www.lillydiabetes.com/</u> or follow us on Twitter: <u>@LillyDiabetes</u> and Facebook: <u>LillyDiabetesUS</u>.

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 <u>lilly.com/newsroom</u>. P-LLY

Lilly Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) and reflects Lilly's current beliefs. Among other things, there is no guarantee that future study results will be consistent with study findings to date. For further discussion of these and other risks and uncertainties, see Lilly's 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.

References

- 1. Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2020. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Dept. of Health and Human Services; 2020.
- 2. International Diabetes Federation. IDF Diabetes Atlas, 9th edn. Brussels, Belgium: International Diabetes Federation, 2019. Available at: http://diabetesatlas.org.

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