

**Patient Information**  
**Humulin® (HU-mu-lin) R U-500**  
**(insulin human)**  
**injection, for subcutaneous use**  
**U-500 (500 units/mL)**

**Do not share your Humulin R U-500 KwikPen or U-500 insulin 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.**

**What is Humulin R U-500?**

- Humulin R U-500 is a man-made insulin that is used to control high blood sugar in adults and children with diabetes mellitus who need more than 200 units of insulin in a day.
- Humulin R U-500 contains **5** times as much insulin (500 units/mL) in 1 mL as Humulin R U-100 (100 units/mL).
- It is not known if Humulin R U-500 is safe and effective when used in combination with other insulins.
- It is not known if Humulin R U-500 is safe and effective when given by continuous subcutaneous infusion.

**Who should not take Humulin R U-500?**

**Do not take Humulin R U-500 if you:**

- are having an episode of low blood sugar (hypoglycemia).
- have an allergy to human insulin or any of the ingredients in Humulin R U-500. See the end of this Patient Information leaflet for a complete list of ingredients in Humulin R U-500.

**What should I tell my healthcare provider before using Humulin R U-500?**

**Before using Humulin R U-500, tell your healthcare provider about all your medical conditions including, if you:**

- have liver or kidney problems.
- take other medicines, especially ones called TZDs (thiazolidinediones).
- have heart failure or other heart problems. If you have heart failure, it may get worse while you take TZDs with Humulin R U-500.
- are pregnant, planning to become pregnant. Talk with your healthcare provider about the best way to control your blood sugar if you plan to become pregnant or while you are pregnant.
- are breast-feeding or plan to breastfeed. Humulin R U-500 may pass into your breast milk. Talk with your healthcare provider about the best way to feed your baby while using HUMULIN R U-500.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, or herbal supplements.

**Before you start using Humulin R U-500, talk to your healthcare provider about low blood sugar and how to manage it.**

**How should I use Humulin R U-500?**

- Read the detailed **Instructions for Use** that come with your Humulin R U-500.
- Use Humulin R U-500 exactly as your healthcare provider tells you to. Your healthcare provider should tell you how much Humulin R U-500 to use and when to use it.
- Know the dose of Humulin R U-500 you use. **Do not** change the dose of Humulin R U-500 you use unless your healthcare provider tells you to.
- Check your insulin label each time you give your injection to make sure you are using the correct insulin.
- **When using the Humulin R U-500 KwikPen:** The Humulin R U-500 KwikPen is specially made to dial and deliver doses of Humulin R U-500 insulin. **Do not** use any syringe to remove Humulin R U-500 from your Humulin R U-500 KwikPen. The markings on certain syringes will not measure your dose correctly. A severe overdose can happen, causing low blood sugar, which may put your life in danger.
- **When using the Humulin R U-500 vial:** **There is a special U-500 insulin syringe to measure Humulin R U-500. Use only a U-500 insulin syringe to draw up and inject your Humulin R U-500.** If you do not use the right syringe type, you may take the wrong dose of Humulin R U-500. This can cause you to have too low blood sugar (hypoglycemia) or too high blood sugar (hyperglycemia). Your healthcare provider should show you how to draw up Humulin R U-500.
- Use Humulin R U-500 **30 minutes** before eating a meal.
- Inject Humulin R U-500 under the skin (subcutaneously) of your upper legs (thighs), upper arms, buttocks or stomach area (abdomen). **Do not** use Humulin R U-500 in an insulin pump or inject Humulin R U-500 into your vein (intravenously).
- **Do not** mix Humulin R U-500 in the KwikPen or vial with any other type of insulin or liquid medicine.

- **Change (rotate) your injection sites within the area you choose with each dose** to reduce your risk of getting lipodystrophy (pits in skin or thickened skin) and localized cutaneous amyloidosis (skin with lumps) at the injection sites.
  - **Do not** use the exact same spot for each injection.
  - **Do not** inject where the skin has pits, is thickened, or has lumps.
  - **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.
- **Check your blood sugar levels.** Ask your healthcare provider what your blood sugars should be and when you should check your blood sugar levels.

**Keep Humulin R U-500 and all medicines out of reach of children.**

**Your dose of Humulin R U-500 may need to change because of:**

- change in level of physical activity or exercise, weight gain or loss, increased stress, illness, change in diet, or because of other medicines you take.

**What should I avoid while using Humulin R U-500?**

While using Humulin R U-500 do not:

- drive or operate heavy machinery, until you know how Humulin R U-500 affects you.
- drink alcohol or use over-the-counter medicines that contain alcohol.

**What are the possible side effects of Humulin R U-500?**

**Humulin R U-500 may cause serious side effects that can lead to death, including:**

- **low blood sugar (hypoglycemia).** Signs and symptoms of low blood sugar may include:
  - dizziness or lightheadedness, sweating, confusion, headache, blurred vision, slurred speech, shakiness, fast heartbeat, anxiety, irritability or mood changes, hunger.
  - your healthcare provider may prescribe a glucagon product for emergency use so that others can give you an injection if your blood sugar becomes too low (hypoglycemic) and you are unable to take sugar by mouth.
- **severe allergic reaction (whole body reaction). Get medical help right away if you have any of these signs or symptoms of a severe allergic reaction:**
  - a rash over your whole body, have trouble breathing, a fast heartbeat, or sweating.
- **low potassium in your blood (hypokalemia).**
- **heart failure.** Taking certain diabetes pills called thiazolidinediones or “TZDs” with Humulin R U-500 may cause heart failure in some people. This can happen even if you have never had heart failure or heart problems before. If you already have heart failure, it may get worse while you take TZDs with Humulin R U-500. Your healthcare provider should monitor you closely while you are taking TZDs with Humulin R U-500. Tell your healthcare provider if you have any new or worse symptoms of heart failure including:
  - shortness of breath, swelling of your ankles or feet, sudden weight gain

Treatment with TZDs and Humulin R U-500 may need to be adjusted or stopped by your healthcare provider if you have new or worse heart failure.

**Get emergency medical help if you have:**

- severe hypoglycemia needing hospitalization or emergency room care, and be sure to tell the hospital staff the units of Humulin R U-500 that your healthcare provider has prescribed for you.
- trouble breathing, shortness of breath, fast heartbeat, swelling of your face, tongue, or throat, sweating, extreme drowsiness, dizziness, confusion.

**The most common side effects of Humulin R U-500 include:**

- low blood sugar (hypoglycemia), 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 of Humulin R U-500.** Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**General Information about the safe and effective use of Humulin R U-500**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. **Do not** use Humulin R U-500 for a condition for which it was not prescribed. **Do not** give Humulin R U-500 to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about Humulin R U-500. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about Humulin R U-500 that is written for healthcare professionals. For more information go to [www.humulin.com](http://www.humulin.com) or call 1-800-545-5979.

**What are the ingredients in Humulin R U-500?**

**Active ingredient:** insulin human

**Inactive ingredients:** glycerin, metacresol, zinc oxide, and Water for Injection as inactive ingredients. Sodium hydroxide and hydrochloric acid may be added to adjust the pH.

**Manufactured by: Eli Lilly and Company, Indianapolis, IN 46285, USA**

**US License Number 1891**

**For more information about Humulin R U-500 go to [www.humulin.com](http://www.humulin.com).**

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