Instructions for Use
Humulin® R U-500
(insulin human)
injection, for subcutaneous use
20 mL multiple-dose vial (500 units/mL)

Please read these instructions before use.

Warnings
• For your safety, always inject Humulin® R U-500 insulin with a U-500 syringe.
• If you use another kind of syringe, you may get a dangerous overdose.

Important Information
• Humulin R U-500 is a concentrated insulin.
• Know your dose. Your health care provider will tell you the number of insulin units that you should take.
• Always inject Humulin R U-500 insulin with a U-500 syringe. Other syringes will not measure your dose correctly.
• If you use the wrong syringe, you can give yourself a severe overdose. This can cause very low blood sugar, which may put your life in danger. For example, using a U-100 syringe can give you a 5 times overdose.
• If you do not have a U-500 syringe, you should contact your health care provider or pharmacist.

Additional Safety Information
• Each line on the U-500 syringe measures 5 units of U-500 insulin.
• You can give from 5 to 250 units in one injection.
• If your dose is more than 250 units, you will need to give more than 1 injection.
• Make sure you know how to draw up your dose with a U-500 syringe. If you need help, call your health care provider.

• **Do not** reuse your U-500 syringe.

• **Do not** share your U-500 syringes with other people. You may give other people a serious infection or get a serious infection from them.

• **Do not** mix Humulin R U-500 with other insulins in the same syringe.

• You can get more instructions by calling Lilly at 1-800-LillyRx (1-800-545-5979).

**Supplies**

- **Humulin R U-500** multiple-dose vial
- **U-500** Syringe (BD [Becton, Dickinson and Company] syringes recommended)
- 2 alcohol swabs
- 1 sharps container

**Before You Start**

- Check your vial. Make sure it says Humulin R U-500.

- Check the expiration date on the vial. **Do not** use it if it is expired. Throw away the opened vial after 40 days, even if there is still insulin left in the vial.

- See if the insulin in the vial is clear. **Do not** use if it is thick, cloudy, or colored or has solid particles.

- Make sure you have a new U-500 Syringe. Check for the green U-500 symbol and green Needle Shield.

- Check your supply. Make sure you have enough Humulin R U-500 insulin and U-500 syringes for several injections. Always reorder **before** you run out.

- Check with your health care provider if you have any questions.

*Use only a U-500 syringe to inject Humulin R U-500 insulin*
Prepare

• Wash your hands with soap and water.
• Always use a **new syringe** for each injection to help prevent infections and blocked needles.

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**Step 1:**
Find the line on the U-500 syringe that matches your prescribed dose. This is your **Dose Line**.
Each line is 5 units.

(Example: Arrow shows Dose Line at 85 units)

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**Step 2:**
If you are using a new vial, pull off the plastic Protective Cap.
Do not remove the Rubber Stopper.

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**Step 3:**
Wipe the Rubber Stopper with an alcohol swab.

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**Step 4:**
Hold the syringe with the Needle pointing up.
Pull down on the Plunger Rod until the Plunger Tip reaches your Dose Line.

(Example Dose: 85 units shown)

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**Step 5:**
Push the Needle through the Rubber Stopper of the vial.
Step 6:
Push the Plunger all the way in. This puts air into the vial.

Step 7:
Turn the vial and syringe upside down and slowly pull the Plunger down until the Plunger Tip is past your Dose Line.

(Example Dose: 85 units
Plunger is shown at 100 units)

If there are air bubbles, tap the syringe gently a few times. This lets the air bubbles rise to the top.

Step 8:
Slowly push the Plunger up until the Plunger Tip reaches your Dose Line.
Check the syringe to make sure that you have the right dose.

(Example Dose: 85 units shown)

Step 9:
Pull the syringe out of the vial’s Rubber Stopper.

Inject
• Inject your insulin exactly as your healthcare provider has shown you.
• Change (rotate) your injection sites within the area you choose for 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 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.
Step 10:
Choose your injection site.
Humulin R U-500 is injected under the skin (subcutaneously). You may inject into your stomach area, buttocks, upper legs, or upper arms.
Wipe the skin with an alcohol swab. Let the injection site dry before you inject your dose.

Step 11:
Insert the Needle into your skin.

Step 12:
Push down on the Plunger to inject your dose.
Then keep the Needle in your skin for at least 5 seconds, to make sure you have injected all of your dose.

Step 13:
Pull the Needle out of your skin.
• You may see blood after you take the Needle out of your skin. This is normal. Press the injection site lightly with a piece of gauze or an alcohol swab. Do not rub the area.
• Do not put the Needle Shield back on the Needle, because you may get a needle stick injury.

Disposal of used syringes
• Put your used syringes in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) syringes in your household trash.
• If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
  - made of a heavy-duty plastic,
  - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
  - upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA’s website at: http://www.fda.gov/safesharpsdisposal.

- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. **Do not** recycle your used sharps disposal container.

**Storage and Handling**

- Keep away from heat and out of direct light.
- Do not shake the vial.

**Unopened vials:**

- Store unopened vials in the refrigerator.
- Do not freeze Humulin R U-500. If it has been frozen, do not use it.
- If unopened vials have been stored in the refrigerator, you may use them until the expiration date.

**After the vial has been opened:**

- Store opened vials in the refrigerator or at room temperature (up to 86°F [30°C]) for up to 40 days.
- Throw away the opened vial after 40 days, even if there is still insulin left in the vial.

**General Information**

- **Always use a U-500 syringe to inject Humulin R U-500 insulin.**
- **Never use other syringes.** The lines and numbers on other syringes will not measure your dose correctly.
- You can give yourself the **wrong dose** if you use any other syringe, such as a U-100, tuberculin or allergy syringe.
  
  For example, a U-100 syringe is made to measure U-100 insulin. If you use a U-100 Syringe for your U-500 dose, **you can give yourself a 5 times overdose.**

- **Do not** make any changes to your dose or the type of insulin you use unless you are told to do so by your health care provider.
- Keep your vials and syringes out of the sight and reach of children.
Frequently Asked Questions

• **Why do I need to use a U-500 syringe?**
  Humulin R U-500 insulin and a U-500 syringe work together to help you inject the correct dose. Using any other syringe may result in dosing mistakes. This may put your life in danger.

• **Do I have to convert my Humulin R U-500 insulin dose when I use the U-500 syringe?**
  No, you do not have to convert your dose. Your health care provider should tell you how much Humulin R U-500 insulin to take in units and when to take it. Your health care provider should show you how to draw up your dose using the U-500 syringe.

• **What should I do if I run out of U-500 syringes?**
  If you run out of U-500 syringes, **do not** use any other syringe to inject Humulin R U-500 insulin. Call your health care provider or pharmacist for help. You may also call Lilly at 1-800-Lilly-Rx (1-800-545-5979).

Where to get more information and help

• If you have any questions about Humulin R U-500 insulin or U-500 syringes, contact Lilly at 1-800-Lilly-Rx (1-800-545-5979).

• You can also call your health care provider or pharmacist.

• For more information on Humulin R U-500 insulin, go to [www.humulin.com](http://www.humulin.com)

Scan this code to launch the humulin.com website

These Instructions for Use have been approved by the U.S. Food and Drug Administration.

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Literature revised: June 2022

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LINR500VL-0004-IFU-20220627