

Instructions for Use

HUMULIN® R U-500 KwikPen®

(insulin human)

injection, for subcutaneous use

3 mL single-patient-use pen (500 units/mL, U-500)



Important:

- **Know your dose of HUMULIN R U-500 insulin.** The Pen delivers your dose in **insulin units**. Insulin units may **not be the same** as syringe markings. **Ask your health care provider what your dose should be for your Pen.**
- Your HUMULIN® R U-500 KwikPen® (Pen) works differently from other pens. It dials 5 insulin units with each click. **Do not count clicks of the dose knob to select your dose. You may get too much insulin or you may not get enough insulin.**
- **HUMULIN R U-500 is a concentrated insulin. Do not transfer HUMULIN R U-500 insulin from your Pen into a syringe. A severe overdose can happen, causing very low blood sugar, which may put your life in danger.**



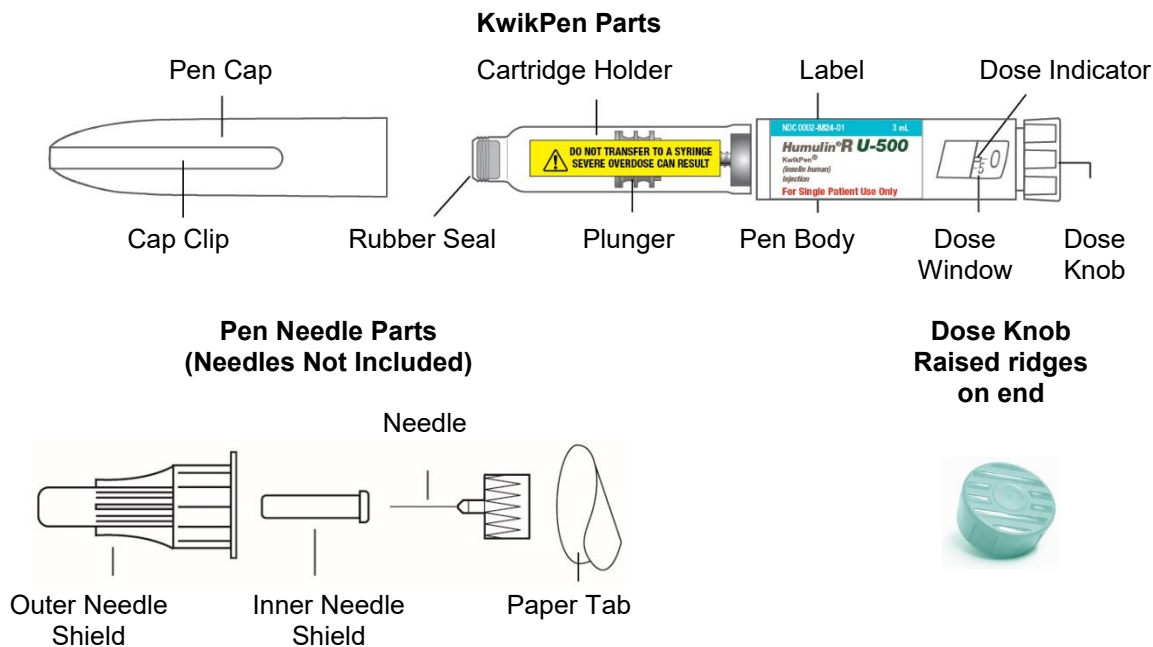
Read the Instructions for Use before you start taking HUMULIN R U-500 and each time you get another Pen. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Do not share your HUMULIN R U-500 Pen 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.

HUMULIN R U-500 KwikPen (“Pen”) is a disposable single-patient-use prefilled pen containing 1500 units of HUMULIN R. You can give yourself more than 1 dose from the Pen. Each turn (click) of the Dose Knob dials 5 units of insulin. You can give from 5 to 300 units in a single injection. The plunger only moves a little with each injection, and you may not notice that it moves. The plunger will only reach the end of the cartridge when you have used all 1500 units in the Pen.

Inject HUMULIN R U-500 only with your Pen. Do not transfer insulin from your Pen to a syringe.

People who are blind or have vision problems should not use the Pen without help from a person trained to use the Pen.



How to recognize your HUMULIN R U-500 KwikPen

- Pen color: Aqua
- Dose Knob: Aqua with raised ridges on the end
- Label: HUMULIN R U-500 and 500 units/mL in a green box

500
units/mL

Supplies needed to give your injection

- HUMULIN R U-500 KwikPen
- KwikPen compatible Needle (Becton, Dickinson and Company Pen Needles recommended)
- Alcohol swab

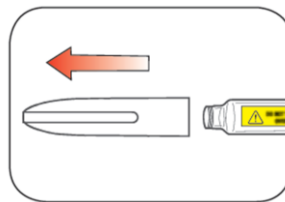
Preparing your Pen

- Wash your hands with soap and water.
- Check the Pen to make sure you are taking the right type of insulin. This is especially important if you use more than 1 type of insulin.
- **Do not** use your Pen past the expiration date printed on the Label or for more than 28 days after you first start using the Pen.
- **Always use a new Needle for each injection to help prevent infections and blocked Needles. Do not reuse or share your needles with other people. You may give other people a serious infection or get a serious infection from them.**

Step 1:

- Pull the Pen Cap straight off.
 - **Do not** remove the KwikPen Label.
- Wipe the Rubber Seal with an alcohol swab.

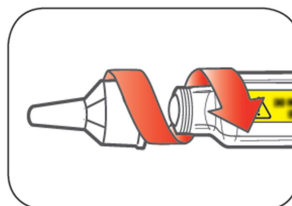
HUMULIN R U-500 should look clear and colorless. **Do not** use if it is cloudy, colored, or has particles or clumps in it.

**Step 2:**

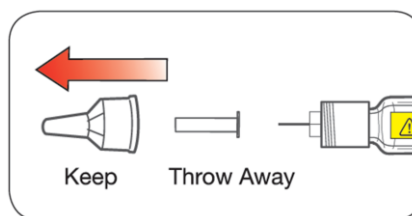
- Select a new Needle.
- Pull off the Paper Tab from the Outer Needle Shield.

**Step 3:**

- Push the capped Needle straight onto the Pen and twist the Needle on until it is tight.

**Step 4:**

- Pull off the Outer Needle Shield. **Do not** throw it away.
- Pull off the Inner Needle Shield and throw it away.



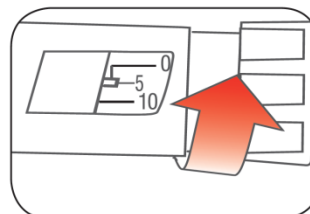
Priming your Pen

Prime before each injection.

- Priming your Pen means removing the air from the Needle and Cartridge that may collect during normal use and ensures that the Pen is working correctly.
- If you **do not** prime before each injection, you may get too much or too little insulin.

Step 5:

- To prime your pen, turn the Dose Knob to **select 5 units**.

**Step 6:**

- Hold your Pen with the Needle pointing up. Tap the Cartridge Holder gently to collect air bubbles at the top.



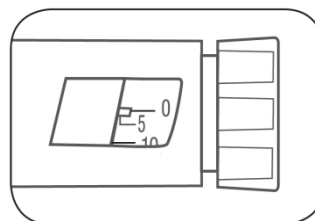
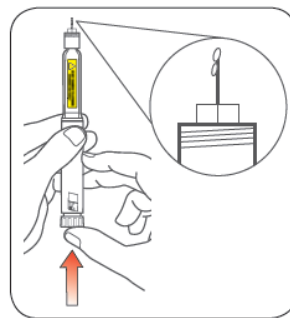
Step 7:

- Continue holding your Pen with Needle pointing up. Push the Dose Knob in until it stops, and “0” is seen in the Dose Window. Hold the Dose Knob in and **count to 5 slowly**.

You should see insulin at the tip of the Needle.

- If you **do not** see insulin, repeat priming steps 5 to 7, no more than 8 times.
- If you **still do not** see insulin, change the Needle and repeat priming steps 5 to 7.

Small air bubbles are normal and will not affect your dose.



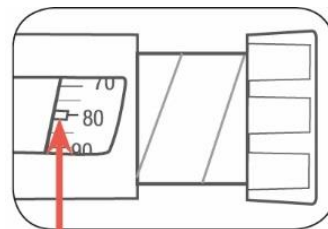
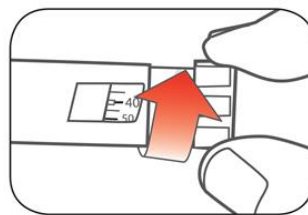
Selecting your dose

This Pen has been made to deliver the dose **in insulin units** that is shown in the Dose Window. Ask your healthcare provider what your dose should be for this Pen.

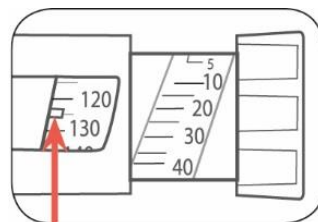
- You can give from 5 to 300 units in a single injection.
- If your dose is more than 300 units, you will need to give more than 1 injection.
 - If you need help with dividing up your dose the right way, ask your healthcare provider.
 - You must use a new Needle for each injection and repeat the priming step.

Step 8:

- Turn the Dose Knob to select the number of units you need to inject. The Dose Indicator should line up with your dose.
 - The Dose Knob clicks as you turn it. Each click of the Dose Knob dials **5 insulin units** at a time.
 - **Do not dial your dose by counting the clicks. You may dial the wrong dose. This may lead to you getting too much insulin or not enough insulin.**
 - The dose can be corrected by turning the Dose Knob in either direction until the correct dose lines up with the Dose Indicator.
 - The **even** numbers (for example, 80) are printed on the dial.
 - The **odd** numbers (for example, 125) are shown as lines between the even numbers.
- **Always check the number in the Dose Window to make sure you have dialed the correct dose.**



Example: 80 units
shown in Dose Window



Example: 125 units
shown in Dose Window

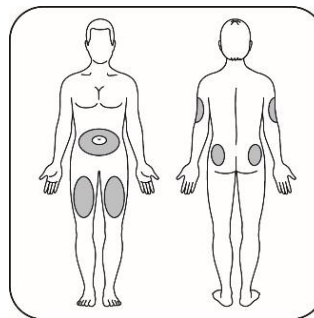
- The Pen will not let you dial more than the number of units left in the Pen.
- If your dose is more than the number of units left in the Pen, you may either:
 - inject the amount left in your Pen and then use a new Pen to give the rest of your dose,
 - or**
 - get a new Pen and inject your full dose.
- It is normal to see a small amount of insulin left in the Pen that you cannot inject. **Do not transfer this to a syringe. Severe overdose can happen.**

Giving your injection

- Inject your insulin 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.
- **Do not** try to change your dose while injecting.

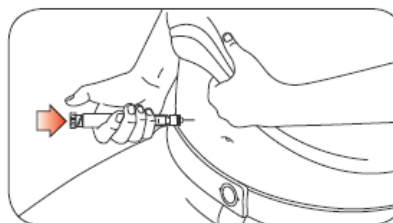
Step 9:

- Choose your injection site.
HUMULIN is injected under the skin (subcutaneously) of your stomach area, buttocks, upper legs or upper arms.
- Wipe your skin with an alcohol swab, and let your skin dry before you inject your dose.



Step 10:

- Insert the Needle into your skin.
- Push the Dose Knob all the way in.



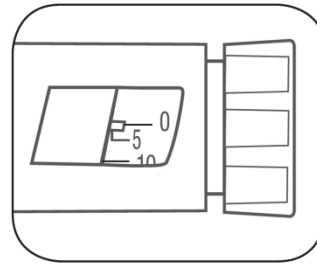
- Continue to hold the Dose Knob in and **slowly count to 5** before removing the Needle.



Do not try to inject your insulin by turning the Dose Knob. You will **not** receive your insulin by turning the Dose Knob.

Step 11:

- Pull the Needle out of your skin.
 - A drop of insulin at the Needle tip is normal. It will not affect your dose.
- Check the number in the Dose Window.
 - If you see “0” in the Dose Window, you have received the full amount you dialed.
 - If you do not see “0” in the Dose Window, **do not** redial. Insert the Needle into your skin and finish your injection.
 - If you **still** do not think you received the full amount you dialed for your injection, **do not start over or repeat your injection**. Monitor your blood glucose as instructed by your healthcare provider.



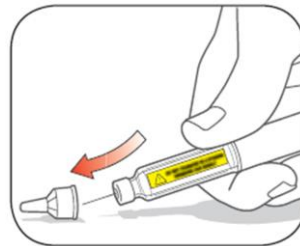
The Plunger only moves a little with each injection, and you may not notice that it moves.

If you see blood after you take the Needle out of your skin, press the injection site lightly with a piece of gauze or an alcohol swab. **Do not** rub the area.

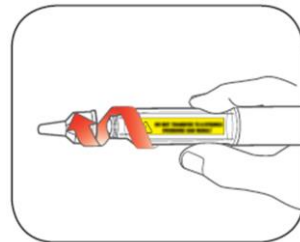
After your injection

Step 12:

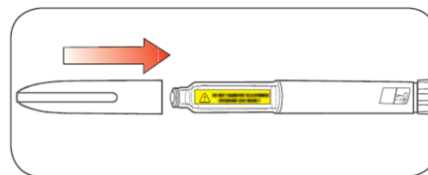
- Carefully replace the Outer Needle Shield.

**Step 13:**

- Unscrew the capped Needle and throw it away (see **Disposing of Pens and Needles** section).
- **Do not** store the Pen with the Needle attached to prevent leaking, blocking the Needle, and air from entering the Pen.

**Step 14:**

- Replace the Pen Cap by lining up the Cap Clip with the Dose Indicator and pushing straight on.



Disposing of Pens and Needles

- Put your used Needles in a FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) loose Needles 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.
- The used Pen may be discarded in your household trash after you have removed the needle.

Storing your Pen

Unused Pens

- Store unused Pens in the refrigerator at 36°F to 46°F (2°C to 8°C).
- **Do not** freeze HUMULIN R U-500. **Do not** use if it has been frozen.
- Unused Pens may be used until the expiration date printed on the Label, if the Pen has been kept in the refrigerator.

In-use Pen

- Store the Pen you are currently using at room temperature up to 86°F (30°C). Keep away from heat and light.
- Throw away the Pen you are using after 28 days, even if it still has insulin left in it.

What you should know if you are switching to HUMULIN R U-500 KwikPen

Ask your healthcare provider what your dose should be for your Pen **in insulin units**. Always follow your healthcare provider's instructions for dosing.

If you are:	It is important to know:
Switching from HUMULIN R U-500 vial (and syringe)	<p>Your Pen may measure your dose differently. The markings in the Dose Window may not be the same as the markings on the syringe you used in the past. If you were using the U-500 syringe to administer your dose, the markings on the syringe may be the same as the markings in the Pen Dose Window.</p> <p>Ask your healthcare provider what dose in insulin units you should dial on your Pen.</p>
Switching from another type of insulin device or pen.	<p>The HUMULIN R U-500 KwikPen is different from other pens. It dials 5 insulin units with each click of the Dose Knob.</p> <p>Do not select your dose by counting clicks. You may get too much insulin or you may not get enough insulin.</p>

General information about the safe and effective use of your Pen

- **Keep your Pen and Needles out of the sight and reach of children.**
- **Do not** use your Pen if any part looks broken or damaged.
- Always carry an extra Pen in case yours is lost or damaged.

Troubleshooting

- If you cannot remove the Pen Cap, gently twist the cap back and forth, and then pull the cap straight off.
- If it is hard to push the Dose Knob:
 - Pushing the Dose Knob more slowly will make it easier to inject.
 - Your Needle may be blocked. Put on a new Needle and prime the Pen.
 - You may have dust, food, or liquid inside the Pen. Throw the Pen away and get a new Pen.

If you have any questions or problems with your HUMULIN R U-500 KwikPen, contact Lilly at 1-800-LillyRx (1-800-545-5979) or call your healthcare provider for help. For more information on HUMULIN R U-500 KwikPen and insulin, go to www.humulin.com.



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www.humulin.com

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Manufactured by:
Eli Lilly and Company
Indianapolis, IN 46285, USA
US License Number 1891

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HUMULIN R U-500 KwikPen meets the current dose accuracy and functional requirements of ISO 11608-1.

Document revision date: June 2022

Lilly (*red script*)
LINR500KP-0005-IFU-20220627