

Instructions for Use
HUMULIN[®] N KwikPen[®]
 (human insulin [rDNA origin] isophane suspension)



Read the Instructions for Use before you start taking HUMULIN N and each time you get another HUMULIN[®] N KwikPen[®]. 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.

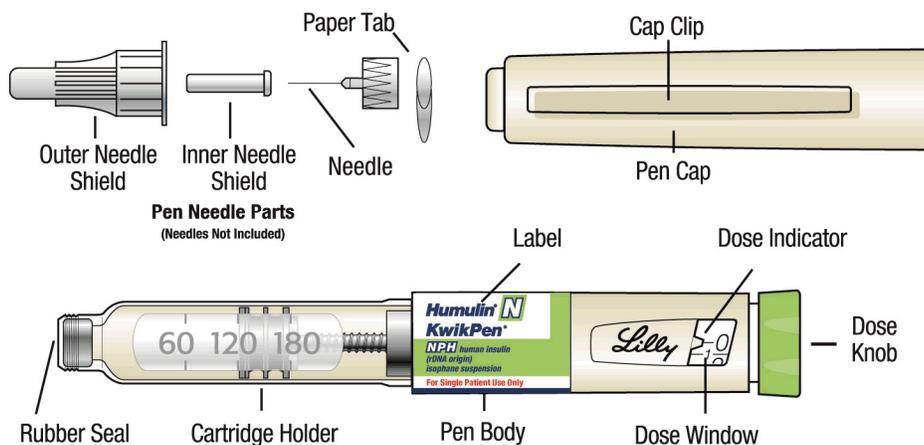
Do not share your HUMULIN N KwikPen with other people, even if the needle has been changed. You may give other people a serious infection or get a serious infection from them.

HUMULIN N KwikPen (“Pen”) is a disposable pen containing 3 mL (300 units) of U-100 HUMULIN[®] N (human insulin isophane suspension [rDNA origin]) insulin. You can inject from 1 to 60 units in a single injection.

HUMULIN N KwikPen has a blue and light green Label with a matching light green Dose Knob (See the KwikPen Parts diagram below).

This Pen is not recommended for use by the blind or visually impaired without the assistance of a person trained in the proper use of the product.

KwikPen Parts

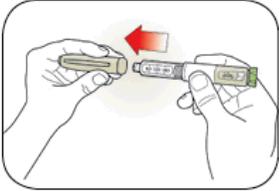
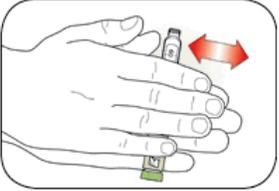
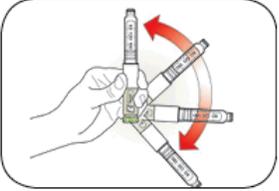


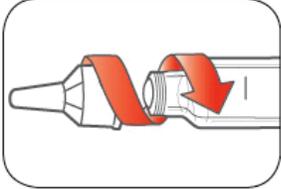
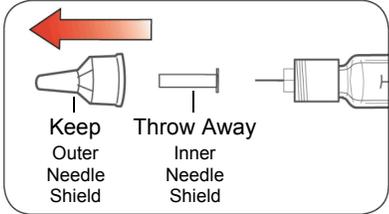
Supplies you will need to give your HUMULIN N injection:

- HUMULIN N KwikPen
- KwikPen compatible Needle (Becton, Dickinson and Company Pen Needles recommended)
- alcohol swab

Preparing HUMULIN N KwikPen:

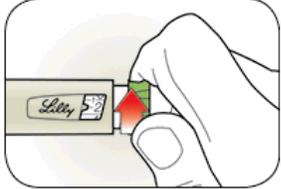
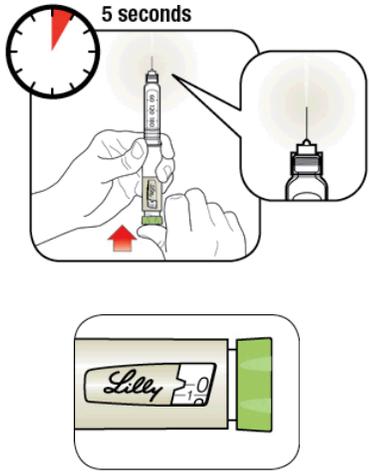
- Wash your hands with soap and water.
- **Check the HUMULIN N KwikPen Label to make sure you are taking the right type of insulin. This is especially important if you use more than 1 type of insulin.**
- **Do not** use HUMULIN N past the expiration date printed on the Label or 14 days after you start using the Pen.
- **Always use a new needle for each injection to help ensure sterility and prevent 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.**

<p>Step 1:</p> <ul style="list-style-type: none"> • Pull the Pen Cap straight off. • Wipe the Rubber Seal with an alcohol swab. <ul style="list-style-type: none"> - Do not twist the cap. - Do not remove the HUMULIN N KwikPen Label. - Do not attach the Needle before mixing. 	
<p>Step 2:</p> <ul style="list-style-type: none"> • Gently roll the Pen between your hands 10 times. 	
<p>Step 3:</p> <ul style="list-style-type: none"> • Move the Pen up and down (invert) 10 times. <p>Mixing by rolling and inverting the Pen is important to make sure you get the right dose.</p> <p>Step 4:</p> <ul style="list-style-type: none"> • Check the liquid in the Pen. HUMULIN N should look white and cloudy after mixing. Do not use if it looks clear or has any lumps or particles in it. 	
<p>Step 5:</p> <ul style="list-style-type: none"> • Select a new Needle. • Pull off the Paper Tab from the Outer Needle Shield. 	

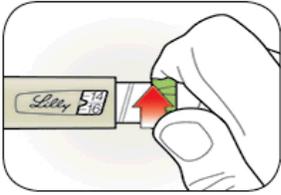
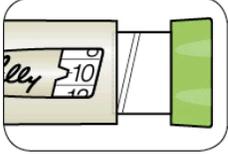
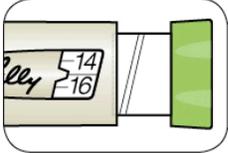
<p>Step 6:</p> <ul style="list-style-type: none"> • Push the capped Needle straight onto the Pen and twist the Needle on until it is tight. 	
<p>Step 7:</p> <ul style="list-style-type: none"> • Pull off the Outer Needle Shield. Do not throw it away. • Pull off the Inner Needle Shield and throw it away. 	

Priming the HUMULIN N KwikPen:

Prime the HUMULIN N KwikPen before each injection. Priming ensures the Pen is ready to dose and removes air that may collect in the cartridge during normal use. If you do not prime before each injection, you may get too much or too little insulin.

<p>Step 8:</p> <ul style="list-style-type: none"> • Turn the Dose Knob to select 2 units. 	
<p>Step 9:</p> <ul style="list-style-type: none"> • Hold the Pen with the Needle pointing up. Tap the Cartridge Holder gently to collect air bubbles at the top. 	
<p>Step 10:</p> <ul style="list-style-type: none"> • Hold the 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. A stream of insulin should be seen from the needle. - If you do not see a stream of insulin, repeat steps 8 to 10, no more than 4 times. - If you still do not see a stream of insulin, change the needle and repeat steps 8 to 10. 	

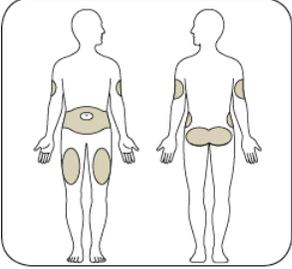
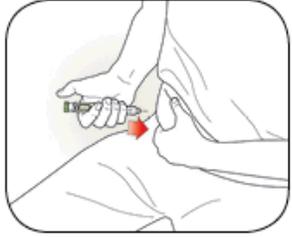
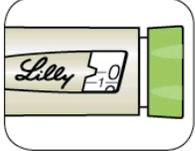
Selecting your dose:

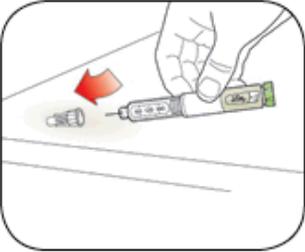
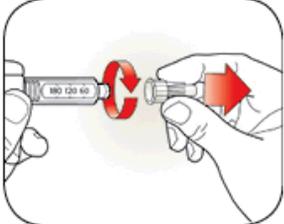
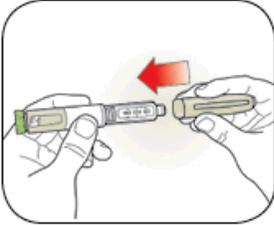
<p>Step 11:</p> <ul style="list-style-type: none"> • Turn the Dose Knob to select the number of units you need to inject. The Dose Indicator should line up with your dose. <p>The dose can be corrected by turning the Dose Knob in either direction until the correct dose lines up with the Dose Indicator.</p> <ul style="list-style-type: none"> - The even numbers are printed on the dial. - The odd numbers, after the number 1, are shown as full lines. 	  <p>(Example: 10 units shown)</p>  <p>(Example: 15 units shown)</p>
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- The HUMULIN N KwikPen 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 the full dose.
- The Pen is designed to deliver a total of 300 units of insulin. The cartridge contains an additional small amount of insulin that cannot be delivered.

Giving your HUMULIN N injection:

- Inject your HUMULIN N exactly as your healthcare provider has shown you.
- Change (rotate) your injection site for each injection.
- **Do not** try to change your dose while injecting HUMULIN N.

<p>Step 12:</p> <ul style="list-style-type: none"> Choose your injection site. <p>HUMULIN N is injected under the skin (subcutaneously) of your stomach area, buttocks, upper legs or upper arms.</p> <ul style="list-style-type: none"> Wipe the skin with an alcohol swab, and let the injection site dry before you inject your dose. 	
<p>Step 13:</p> <ul style="list-style-type: none"> Insert the Needle into your skin. 	
<p>Step 14:</p> <ul style="list-style-type: none"> Put your thumb on the Dose Knob and push the Dose Knob in until it stops. Hold the Dose Knob in and slowly count to 5. 	
<p>Step 15:</p> <ul style="list-style-type: none"> Pull the Needle out of your skin. <p>You should see “0” in the Dose Window. If you do not see “0” in the Dose Window, you did not receive your full dose.</p> <ul style="list-style-type: none"> 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. A drop of insulin at the needle tip is normal. It will not affect your dose. If you do not think you received your full dose, do not take another dose. Call Lilly at 1-800-LillyRx (1-800-545-5979) or your healthcare provider for help. 	

<p>Step 16:</p> <ul style="list-style-type: none"> Carefully replace the Outer Needle Shield. 	
<p>Step 17:</p> <ul style="list-style-type: none"> Unscrew the capped Needle and throw it away. Do not store the Pen with the Needle attached to prevent leaking, blocking of the Needle, and air from entering the Pen. 	
<p>Step 18:</p> <ul style="list-style-type: none"> Replace the Pen Cap by lining up the Cap Clip with the Dose Indicator and pushing straight on. 	

After your injection:

- 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.

How should I store my HUMULIN N KwikPen?

- Store unused HUMULIN N KwikPens in the refrigerator at 36°F to 46°F (2°C to 8°C). The Pen you are currently using should be stored at room temperature, below 86°F (30°C).
- **Do not** freeze HUMULIN N. **Do not** use HUMULIN N if it has been frozen.
- Unused Pens may be used until the expiration date printed on the Label, if kept in the refrigerator.
- The HUMULIN N Pen you are using should be thrown away after 14 days, even if it still has insulin left in it.
- Keep HUMULIN N away from heat and out of the light.

General information about the safe and effective use of HUMULIN N KwikPen.

- **Keep HUMULIN N KwikPen and needles out of the reach of children.**
- **Always** use a new needle for each injection.
- **Do not share your Pen or needles with other people. You may give other people a serious infection or get a serious infection from them.**
- **Do not** use the Pen if any part looks broken or damaged.
- Always carry an extra Pen in case yours is lost or damaged.
- If you cannot remove the Pen Cap, gently twist the Pen Cap back and forth, and then pull the Pen Cap straight off.
- If it is hard to push the Dose Knob or the Pen is not working the right way:
 - 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 one.
 - It may help to push the Dose Knob more slowly during your injection.
- Use the space below to keep track of how long you should use each HUMULIN N KwikPen.
 - Write down the date you start using your HUMULIN N KwikPen. Count forward 14 days.
 - Write down the date you should throw it away.

Example:

First used on _____ + 14 days = Throw out on _____

Date

Date

Pen 1 - First used on _____ Throw out on _____

Date

Date

Pen 2 - First used on _____ Throw out on _____

Date

Date

Pen 3 - First used on _____ Throw out on _____

Date

Date

Pen 4 - First used on _____ Throw out on _____

Date

Date

Pen 5 - First used on _____ Throw out on _____

Date

Date

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

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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Revised: March 12, 2015

Marketed by: Lilly USA, LLC

Indianapolis, IN 46285, USA

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HUMULIN N KwikPen meets the current dose accuracy and functional requirements of ISO 11608-1:2000.

LINNKP-0002-IFU-20150312