SECTION 1 Read this section completely before you begin. Then, move on to Section 2.

WHAT YOU NEED TO KNOW ABOUT THE HUMATROPEN® 6 MG

Read these instructions carefully BEFORE using your HumatroPen® 6 mg. You need to use the Pen correctly in order to get the most benefit from the Humatrope® treatment. Failure to follow these instructions completely may result in too much or too little Humatrope® being injected.

INTRODUCTION

The HumatroPen® is an injection device intended for use with Humatrope® Cartridges. Your healthcare professional has prescribed the Humatrope® and that you use this product as prescribed.

DO NOT CHANGE the dose or Pen unless directed by your healthcare professional.

Before using your HumatroPen® 6 mg, make sure that you thoroughly read this manual. It explains the Pen operation and has a troubleshooting guide, should questions arise.

If you have any questions about your HumatroPen® 6 mg, please contact your healthcare professional or call Lilly Customer Service at 1-800-545-5972.

WARNING: DO NOT USE the HUMATROPEN 6 mg INJECTION DEVICE AND HUMATROPE CARTRIDGES IF YOU ARE ALLERGIC TO METACRESOL OR GLYCERIN.

IMPORTANT INFORMATION ABOUT THE HUMATROPEN® 6 MG

• Where you are using this manual, please pay special attention.
• DO NOT USE the Pen if any part of the Pen or Cartridge appears broken or damaged. Contact your healthcare professional or the Lilly Customer Response Centre at 1-800-545-5972.
• Confirm that you have a 6 mg HumatroPen® Cartridge to match the HumatroPen® 6 mg. It is not compatible with 3 mg or 12 mg Cartridges. If it does not match DO NOT USE and contact your healthcare professional.
• ONLY follow Section 2 if you start use of a new Cartridge after first use of each new Cartridge.
• Section 3 of this manual should be followed for daily injections.
• DO NOT SHAKER your HumatroPen® 6 mg Pen or Cartridges as this may risk transmission of infectious agents.

The HumatroPen® is not recommended for use by blind or visually impaired individuals without the assistance of a sighted individual trained in its use.

ABOUT PEN NEEDLES

What kinds of Needles can be used with the HumatroPen® 6 mg?

• Pen Needles are not included. Your pharmacist will prescribe the needles to your prescription.
• Be sure to check the Cartridge:
  • For expiration date
  • To ensure the Cartridge is the correct strength on the Cartridge label.
• Ask your healthcare professional what Needle gauge and length is best for you.

Most a new Needle be used for each injection.

• Yes, a new needle must be used for each injection.
• Remove the Needle from the HumatroPen® 6 mg prior to returning the device to its case. Use a new Needle for each injection. Using a new Needle for each injection will help minimize the risk of infection, prevent leakage of Humatrope, prevent air bubbles from entering the cartridge, and reduce Needle clogs.

How do I throw away used Needles?

• Throw away used Needles as directed by your healthcare professional.

CARE AND STORAGE OF THE HUMATROPEN® 6 MG

Cautions

• These parts can be cleaned with a damp cloth. DO NOT USE alcohol or other cleaning agents.
• DO NOT SOAK or immerse the Pen in liquid.
• DO NOT APPLY oil or any other lubricant.
• DO NOT APPLY any other substance.

Protect the pen and case from moisture especially when transporting in the travel cooler bag.

Storage

• Store the HumatroPen® 6 mg with attached Humatrope® Cartridge in the storage case or its container until the time of the next injection. DO NOT FREEZE.
• All HumatroPen® Cartridges and Cartridges must be refrigerated at temperatures between 2°C and 8°C (36°F to 46°F).
• DO NOT FREEZE. A prepared Cartridge can be left on a Pen for 20 days in the refrigerator. DO NOT USE any prepared Cartridges after 20 days.
• Let the HumatroPen® 6 mg Pen and attached Humatrope Cartridge stand at room temperature for 10 minutes before injecting. Discomfort may be noticed at the injection site if Humatrope is injected cold.
• Daily room temperature exposure should not exceed 30 minutes.
• DO NOT STORE the Pen with the Needle attached.

REPLACEMENT

The HumatroPen® 6 mg has been designed to be used for up to 3 years after first use. Record the date the Pen was first used here /_/_/ _._._. Contact your healthcare professional if a new 6 mg Pen is needed, or when the Pen has been used for 3 years.

HumatroPen® 6 mg Limited Warranty

ELI LILLY CANADA INC. (“ELI LILLY”) warrants the HumatroPen® 6 mg against defects in workmanship and materials for a period of three years from the date of its receipt by the original user. This warranty is NONTRANSFERABLE and NONASSIGNABLE.

If the HumatroPen® 6 mg fails to function during the warranty period, ELI LILLY will replace the pen at ELI LILLY’s expense. In order to return the Pen for replacement, the original user must notify ELI LILLY’s Customer Response Centre at 1-800-545-5972 of the problem. ELI LILLY will replace the HumatroPen® 6 mg with a new HumatroPen® 6 mg.

This limited warranty is exclusive except to the extent of any warranty, implied or other, for merchantability or fitness for a particular purpose made by ELI LILLY. ELI LILLY will not be liable for any indirect, special, or consequential damages, whether based on contract, tort, or strict liability, or any other legal theory. Some provinces may not allow the exclusion or limitation of incidental, consequential or other damages, so some or all of this exclusion may not apply to you. THIS THREE-YEAR LIMITED WARRANTY IS IN LIEU OF AND SPECIFICALLY EXCLUDES AND DISCLAIMS ALL OTHER EXPRESS OR IMPLIED WARRANTIES, WHETHER WRITTEN OR ORAL, OR ANY OTHER FORM, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. SOME PROVINCES MAY NOT ALLOW THE EXCLUSION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO SOME OR ALL OF THIS EXCLUSION MAY NOT APPLY TO YOU. This Limited Warranty gives you specific legal rights. You may have other rights that vary from province to province.

For more information on the accompanying complete HumatroPen® 6 mg User Manual, contact ELI LILLY at 1-800-545-5972.

SECTION 2 Read and follow the directions in this section only after you have read Section 1.

GETTING STARTED

Be sure to read the reconstitution (mixing) directions as described in the Humatrope® Kit. Perform the New Cartridge Setup only once at the beginning of each new Cartridge. For daily use, DO NOT REPEAT this one-time-only New Cartridge Setup. If you do, you may run out of Humatrope early.

NEW CARTRIDGE SETUP

STEP A - CHECK THE PEN AND CARTRIDGE

Be sure to check the Cartridge:
• For 6 mg Cartridge Label
• For expiration date
• Contents should be clear and free of particles

DO NOT USE the HumatroPen® 6 mg Pen if the Cartridge appears broken or damaged. Contact your healthcare professional.

If the Cartridge is not completely attached, the Screw may come off and an incorrect dose may be given.

STEP B - ATTACH THE CARTRIDGE

Use the White Tip of the Cartridge to push the Dose Lock.

The screw may not be out when you get the Pen.

If the Cartridge is not completely attached, the Screw may come off and an incorrect dose may be given.

STEP C - ATTACH THE NEEDLE

Remove the Paper Tab from the end of the Dose Cup.

Push the Needle straight into the 6 mg Cartridge and screw on clockwise until secure.

STEP D - REMOVE AIR FROM NEW CARTRIDGE

Push the Needle straight up.

Pull off the Dose Cup and the Inner Cap.

Keep the Dose Cup to remove the Needle after your injection.

STEP E - CONTINUE ON DAILY USE

• The Pen and cartridge must be set up before injecting the first dose from each new Cartridge.
• Set up the new Cartridge is important to remove large air bubbles that may be present after reconstitution (mixing).
• If a needle is not used after several attempts, contact your healthcare professional or call Lilly at 1-800-545-6872.
• The Needle Cover should not be used during the pen cartridge set-up.

Cartridge Setup is only done at the start of each new cartridge.

Leave the Cartridge attached and DO NOT REMOVE until the Cartridge is empty.

Be to Section 3, Step 3, for instructions on how to inject the first dose.
SECTION 3

DAILY USE

STEP 1 - CHECK THE PEN

Pull off the Pen Cap.

• DO NOT USE the Pen if any part of the Pen or Cartridge appears broken or damaged. Contact your healthcare professional.

• Be sure to check the Cartridge:
  • For long Cartridge Label
  • For expiration date
  • Capsules should be clean and free of particles

Look at the Injection Button and the Front Housing to confirm it is a 6 mg Pen.

• Check that the number on the Front Housing matches the Cartridge strength on the Cartridge Label. If the Pen and Cartridge do not match, contact your healthcare professional.

STEP 2 - ATTACH THE NEEDLE

• Remove the Paper Tab from the end of the Dose Cap.

• Holding the Needle by the outer ring, push the Needle straight onto the 6 mg Cartridge and screw on clockwise until secure.

• Pull off the Dose Cap and the Paper Tab.

• Hold the Needle Cover available separately from the HumatroPen 6 mg Kit. Refer to the HN Cover user manual for instructions.

STEP 3 - DIAL AND INJECT THE DOSE

Transact Dose Knob to desired dose.

• 0.25 mg shown in the drawing above.

• If you dial past the desired dose, you can correct the dose by dialing backwards.

Insert the needle as directed by your healthcare professional.

• Place your thumb on the Injection Button and firmly push in on the Button.

Maintain pressure on the Injection Button for several seconds, then remove Needle from the skin.

Check to ensure you see a 0.00 in the Dose Window to confirm you received the complete dose.

STEP 4 - REMOVE AND DISPOSE OF THE NEEDLE

Carefully replace the Dose Cap, unattached by your healthcare professional.

While holding the cartridge in one hand, unscrew the capped Needle by turning counter-clockwise. Discard the Needle as directed by your healthcare professional.

Replace the Pen Cap.

• DO NOT STORE the Pen with a Needle attached to prevent air from entering the Cartridge.

• DO NOT REMOVE this Cartridge from the Pen until the Cartridge is empty or needs to be replaced to avoid the possibility of an inaccurate dose.

STEP 5 - STORE PEN AND CARTRIDGE FOR NEXT USE

Store the HumatroPen 6 mg properly. (See “Care and Storage for the HumatroPen 6 mg” in Section 2 for all of your instructions.)

When it is time for your next routine dose, go to Section 3, and repeat Steps 1-5.

SECTION 4

COMMONLY ASKED QUESTIONS

1. Do I need to perform new Cartridge Setup before every dose?

• No. The New Cartridge Setup is done only once for each cartridge, just before a new cartridge is used for the first time.

• The purpose of the setup is to make sure the HumatroPen 6 mg and 6 mg Cartridge are ready to use.

• Try to repeat the New Cartridge Setup before each routine dose, you may run out of Humatrope early. The small amount of product used in the New Cartridge Setup will not affect the supply of Humatrope.

2. What should I do if the Cartridge Label and Pen do not match?

• DO NOT USE the Pen if the Cartridge strength on the Humatrope cartridge label does not match the number on the Pen’s Front Housing.

• Contact your healthcare professional for assistance or to obtain a replacement.

3. What should I do if the HumatroPen is not clear after mixing?

• Be sure to gently invert the Pen up and down 10 times. DO NOT SHAKE. Then, let the Pen sit or lay flat for three minutes. If the solution remains cloudy or has particles, gently invert the Pen up and down 10 more times. Let the Pen sit for five more minutes.

• If the solution remains cloudy or contains particles after reconstitution (mixing), DO NOT USE. Contact your healthcare professional for assistance or Lilly at 1-800-545-0972.

4. Why are there air bubbles in the Cartridge?

• Air bubbles may remain in the Cartridge after reconstitution (mixing).

• If the Pen is stored with a Needle attached, air bubbles may form in the Cartridge.

• The Screw may not move out when you push the Injection Button unless there is a Cartridge in the Pen.

• If the Pen is stored with a Needle attached, air bubbles may form in the Cartridge.

• Check that the Cartridge is not damaged or broken.

• You may not have received your f

5. Why doesn’t the Screw move out when there is no Cartridge attached to the Pen?

• If the Pen is stored with a Needle attached, air bubbles may form in the Cartridge.

• The Screw may not move out when you push the Injection Button until a Cartridge is attached. The Screw will move out when the Injection Button is pushed.

6. Why should I do it if I can’t attach the Cartridge to the Pen Body?

• Check that the Cartridge is not damaged or broken.

• Carefully line up the Cartridge with the Pen Body and screw together until secure. If the Cartridge and Pen cannot be screwed together contact your healthcare professional.

7. Why is it difficult to push the Injection Button when I try to inject the dose?

• The Needle may have a blockage. Try attaching a new Needle.

• Pushing the Injection Button down quickly may make the Injection Button harder to push. Pushing the Injection Button more slowly may make it easier.

• Using a larger diameter Needle will make it easier to push the Injection Button during injection. Ask your healthcare professional which Needle is best for you.

• The Injection Button may become harder to push if the inside of your Pen gets dirty with Humatrope, food, drink or other materials.

8. Why doesn’t the Dose Knob go all the way in when I inject the dose?

• This can happen if the HumatroPen Cartridge does not have enough Humatrope left in it for the full dose. It is possible to set a dose larger than the amount of Humatrope left in the Cartridge. At the end of the injection, the number in the Dose Window should be 0.00. If it is not, this is the amount of Humatrope you DO NOT receive.

• Contact your healthcare professional on how to handle a partial dose. Remove the Needle and empty Cartridge.

• For the next daily use attach a new Cartridge as shown in Section 2, Step A, and continue with New Cartridge Setup (Section 2).

9. Why do I use HumatroPen leaking from the Needle after I have finished the injection?

• It is normal for a single drop to remain on the tip of the Needle after the injection is complete. If you see more than one drop:
  • You may not have received your full dose. DO NOT INJECT another dose. Consult with your healthcare professional for assistance.
  • To prevent this, for your next dose, firmly push and hold the Injection Button in and slowly count to five before removing the needle from the skin (see Sections 3, Step D).

10. How can I tell when the injection is complete?

• The injection is complete when:
  • You have slowly counted to five while you are still holding the Injection Button in and before you remove the Needle from the skin.
  • 0.00 is in the center of the Dose Window.

11. What should I do if I did not get my prescribed dose?

• If you dial a dose higher than your prescribed dose, just dial the knob back to your prescribed dose without putting in the Injection Button.

• If you dial a dose higher than your prescribed dose, just dial the knob back to your prescribed dose without putting in the Injection Button.

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