

[H Block graphic]

Humatrope®
somatropin

HUMATROPEN® 12 mg

Growth Hormone Delivery
System

Injection Device for Use
with Humatrope®
(somatropin) Cartridges



12
mg

www.lilly.ca

The Lilly logo, which is the word "Lilly" in a red, cursive script font.

PEN USER MANUAL

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

WHAT YOU NEED TO KNOW ABOUT THE HUMATROPEN 12 MG

Read these instructions carefully BEFORE using your HumatroPen 12 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

Intended Use:

The HumatroPen 12 mg is a reusable pen-injector designed for self-administration of human growth hormone. The pen-injector is intended for use with the specified Humatrope 12 mg Cartridges and single use, detachable and disposable pen needles (supplied separately).

Contraindications:

There are no known contraindications for HumatroPen 12 mg.

Your healthcare professional has prescribed the Humatrope dose and Pen that you or your child should receive.


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

Before using your HumatroPen 12 mg, make sure that you thoroughly read this Pen User Manual. It explains the Pen operations and has a troubleshooting guide, should questions arise.

These instructions do not take the place of talking with your healthcare professional about your medical condition or your treatment. If you have any questions or problems with your HumatroPen 12 mg, please contact your healthcare professional or call Lilly Customer Response Centre at 1-888-545-5972.


WARNING: DO NOT USE THE HUMATROPEN 12 mg INJECTION DEVICE AND HUMATROPE CARTRIDGES IF YOU ARE ALLERGIC TO METACRESOL OR GLYCERIN.

IMPORTANT INFORMATION ABOUT THE HUMATROPEN 12 MG

- 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 1-888-545-5972.
- Confirm that you have a 12 mg Humatrope Cartridge to match the HumatroPen 12 mg. If it does not match DO NOT USE and contact your healthcare professional.
- ONLY follow Section 2 to set up a new Cartridge before first use of each new Cartridge.
- Section 3 of this manual should be followed for every injection.
-  DO NOT SHARE your HumatroPen 12 mg or Pen Needles as this may risk transmission of infectious agents.
- The HumatroPen 12 mg 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 12 mg?

- Pen Needles are not included. You may need a prescription to get the Needles from your pharmacist.
- Becton, Dickinson and Company Pen Needles are recommended for use with the HumatroPen 12 mg.
- Use of the Hidden Needle Cover with your HumatroPen is optional.
- **When using the Hidden Needle Cover with your HumatroPen, you must use a Needle length of 5 mm or greater.**
-  Refer to the Hidden Needle Cover User Manual for instructions.
- Ask your healthcare professional what Needle gauge and length is best for you.

Must a new Needle be used for each injection?

- Yes, a new Needle must be used for each injection.
- Remove the Needle from the HumatroPen 12 mg prior to returning the device to its storage 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?

- Refer to SECTION 3, STEP 4.

CARE AND STORAGE FOR THE HUMATROPEN 12 MG

Care

- Soiled parts can be cleaned with a damp cloth. DO NOT USE alcohol or other cleaning agents.



- Keep dry.
- DO NOT APPLY oil or any other lubricant.
- Protect the Pen and storage case from moisture especially when transporting in the travel cooler bag.

Storage



- Temperature limit.
- Store HumatroPen 12 mg between -40°C (-40°F) to 70°C (158°F) without the Humatrope 12 mg Cartridge.
- Store the HumatroPen 12 mg with attached Humatrope Cartridge in the storage case in the refrigerator until the time of the next injection. **DO NOT FREEZE.**
- All Humatrope Cartridges and diluent must be refrigerated at temperatures between +2°C and +8°C (36° to 46°F). **DO NOT FREEZE.** A prepared Cartridge can be left on a Pen for 28 days in the refrigerator. DO NOT USE any prepared Cartridge after 28 days.
- Let the HumatroPen 12 mg with 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 and DISPOSAL OF PEN

Do not use your Pen for more than 3 years after the first use or past the Use-by (expiration) date on the carton, whichever comes first.

The expired pen may be discarded in your household trash after you have removed the needle. Dispose of the expired Pen as instructed by your healthcare professional after you have removed the Needle.

Record the date the Pen was first used here: ___ / ___ / ___.

Record the Use-by date from your carton here: ___ / ___ / ___.

Contact your healthcare professional if you need a new HumatroPen 12 mg.

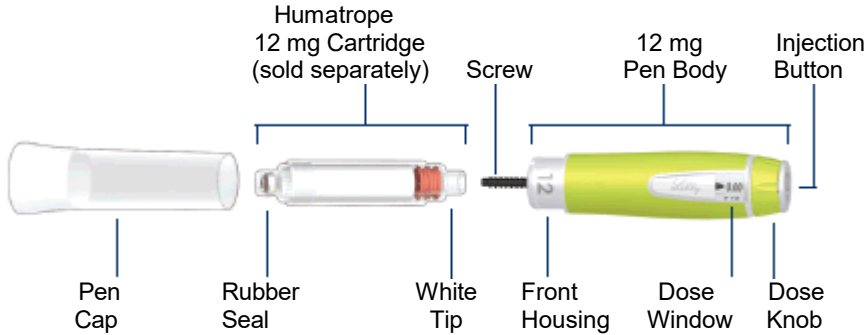


Please see the accompanying complete Humatrope *Patient Information Sheet*.

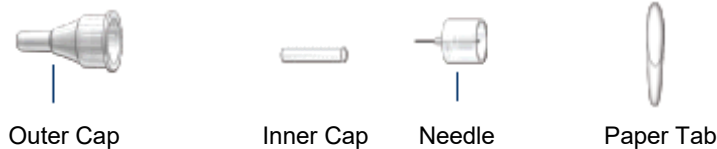


For additional information, call 1-888-545-5972 or visit our website at www.lilly.ca.

HUMATROPEN 12 MG PARTS



PEN NEEDLE PARTS (PEN NEEDLES NOT INCLUDED)



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

GETTING STARTED

Be sure to follow the reconstitution (mixing) directions as described in the Humatrope Cartridge 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

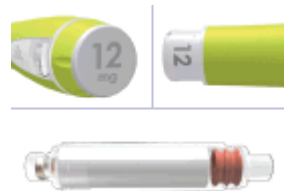


Be sure to check the Cartridge:

- For 12 mg Cartridge Label
- For expiration date
- Contents should be clear and free of particles



Pull off the Pen Cap.



Look at the Injection Button and the Front Housing to confirm it is a 12 mg Pen.

NOTE

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



CHECK

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 B - ATTACH THE CARTRIDGE



Use the White Tip of the Cartridge to push the Screw back.



Push the White Tip of a reconstituted Cartridge into the Pen Body. Screw the 12 mg Pen Body onto the Cartridge until it is secure.



CHECK

Look at the Injection Button and the Front Housing to confirm it is a 12 mg Pen.

NOTE

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

NOTE

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

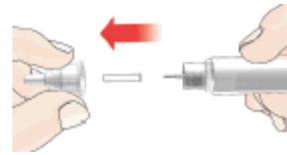
STEP C - ATTACH THE NEEDLE



Remove the Paper Tab from the end of the Outer Cap.



Push the Needle **straight** onto the 12 mg Cartridge and screw on clockwise until secure.

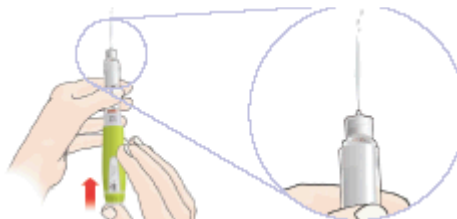


- Pull off the Outer Cap and the Inner Cap.
- Keep the Outer Cap to remove the Needle after your injection.

STEP D – REMOVE AIR FROM NEW CARTRIDGE



Dial 2.50 mg.



- Point the Needle straight up.
- Push the Injection Button and hold for five seconds.
- Dial 0.10 mg and repeat these steps until you see a stream of liquid.

NOTE

- The Pen and Cartridge must be set up before injecting the first dose from **each new 12 mg Cartridge**.
- Setting up the new Cartridge is important to remove large air bubbles that may be present after reconstitution (mixing).
- If a stream is not seen after several attempts, contact your healthcare professional or Lilly at **1-888-545-5972**.
- The Hidden Needle Cover should not be used during the Pen and Cartridge set up.

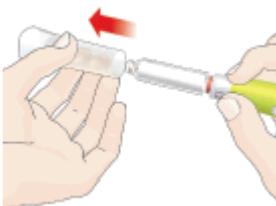
STEP E – CONTINUE ON TO DAILY USE

- Cartridge Setup is only done at the start of every new Cartridge.
- Leave the Cartridge attached and **DO NOT REMOVE** until the Cartridge is empty.
- Go to Section 3, Step 3, for instructions on how to inject the first dose.

Section 3 Now that you have done the one-time-only New Cartridge Setup, follow Section 3 for all of your injections.

DAILY USE

STEP 1 – CHECK THE PEN



Pull off the Pen Cap.

Be sure to check the Cartridge:

- For 12 mg Cartridge Label
- For expiration date
- Contents should be clear and free of particles

Look at the Injection Button and the Front Housing to confirm it is a 12 mg Pen.

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



CHECK
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.

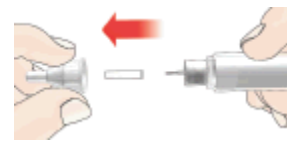
STEP 2 – ATTACH THE NEEDLE



- Remove the Paper Tab from the end of the Outer Cap.



Holding the Needle by the outer cap, push the Needle **straight** onto the 12 mg Cartridge and screw on clockwise until secure.



- Pull off the Outer Cap and the Inner Cap.
- Keep the Outer Cap to remove the Needle after the injection.

NOTE

Use of the Hidden Needle Cover with your HumatroPen is optional. When using the Hidden Needle Cover with your HumatroPen, you must use a Needle length of 5 mm or greater. Refer to the Hidden Needle Cover Instructions for Use.

STEP 3 – DIAL AND INJECT THE DOSE



Turn the Dose Knob to desired dose.

EXAMPLE

0.50 mg shown in the drawing above.

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

The dose knob clicks as you turn it. **DO NOT** dial your dose by counting clicks because you may dial the wrong dose.



Insert the Needle as directed by your healthcare professional.

Place your thumb on the Injection Button, then slowly and firmly push the Injection Button until it stops moving.

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

Check to make sure you see a **0.00** in the Dose Window to confirm you received the complete dose.



NOTE

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 **DID NOT** receive.

Consult with 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).

STEP 4 – REMOVE AND DISPOSE OF THE NEEDLE



 Carefully replace the Outer Needle Cap as instructed by your healthcare professional.



- While holding the cartridge in one hand unscrew the capped Needle by turning counter-clockwise.
-  Put used Needles in a sharps container or a hard plastic container with a secure lid. Do not throw Needles directly into your household trash.
- Do not recycle the filled sharps container.
- Ask your healthcare provider about options to dispose of the sharps container properly.
- The directions regarding Needle handling are not



Replace the Pen Cap.

intended to replace local
healthcare provider or
institutional policies.

NOTE

- **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 12 mg properly. (See “Care and Storage for the HumatroPen 12 mg” in **Section 1** of this Pen User Manual for more information.)

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 the 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 Humatrope 12 mg Cartridge with the HumatroPen 12 mg are ready to use.
- If you 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 Humatrope 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 for at least 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 **1-888-545-5972**.

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. **DO NOT STORE** the Pen with a Needle attached.
- Perform the New Cartridge Setup to remove air bubbles from the Cartridge.
- Small air bubbles are normal. They will not harm you nor affect the dose.

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

- The Screw may not move out when you push the Injection Button unless there is a Cartridge in the Pen. This feature allows you to easily push the Screw into the Pen Body when replacing a Cartridge.
- Once a Cartridge is attached, the Screw will move out when the Injection Button is pushed.

6. What should I do 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 be clogged. 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 to zero when I inject the dose?

- This can happen if the Humatrope 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 DID NOT receive. Consult with 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 see Humatrope 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 Section 3, Step 3).

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.

AND

- **0.00** is in the center of the Dose Window.

11. What do I do if I dial past my prescribed dose?

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

If you have any questions or problems with your HumatroPen 12 mg, contact Lilly at 1-888-545-5972 or your healthcare professional for assistance.

Report all MEDICAL DEVICE COMPLAINTS or UNDESIRABLE SIDE EFFECTS, including SUSPECTED SERIOUS INCIDENTS, to Eli Lilly and company, by contacting them at 1-888-545-5972.

You are also encouraged to report all UNDESIRABLE SIDE EFFECTS, including SUSPECTED SERIOUS INCIDENTS, to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345



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Eli Lilly and Company
Pharmaceutical Delivery Systems
Lilly Corporate Center, Indianapolis, IN 46285, USA

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Eli Lilly Canada Inc.
130 King Street West, P.O. Box 73
Toronto, Ontario
M5X 1B1






Eli Lilly Nederland B.V.
Papendorpseweg 83
3528 BJ UTRECHT
The Netherlands

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The HumatroPen[®] 12 mg meets the current dose accuracy and functional requirements of ISO 11608-1 and is for use with Humatrope[®] 12 mg Cartridges only.

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





Non-harmonized Symbol Glossary¹

	Patient information website
	Medical Device ²
	Single Patient – Multiple Use ²

¹ Glossary includes non-harmonized symbols used in the labeling.

² Symbol used only on the carton.

International Organization for Standards (ISO) Symbol Glossary¹

	Caution ²
	Keep dry ³
	Temperature limit ³
	Consult instructions for use ³
	Manufacturer ³
	Catalogue number ⁴
	Batch code ⁴
	Use-by date ⁴

¹ Glossary includes only ISO symbols used in the labelling.

² ISO Symbol used only on the pen user manual (UM).

³ ISO Symbol used on both the pen user manual (UM) and carton

⁴ ISO Symbol used only on the carton

The information in this document is current as of the revision date shown below. For the most current information, please visit our website at www.lilly.ca or contact us directly at 1-888-545-5972.

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