



PV 6510 AMP

HumatroPen® 12 mg

Growth Hormone Delivery System

Injection Device for Use with Humatrope® (somatropin (cDNA origin) for injection) Cartridges

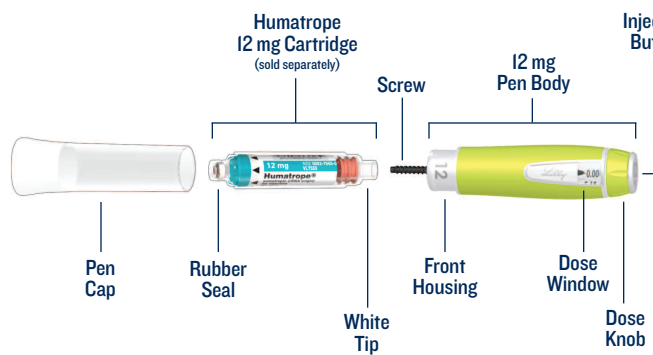


PEN USER MANUAL

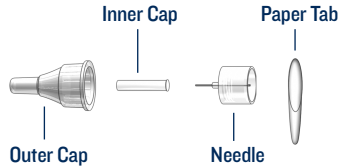
12 mg



HUMATROPEN 12 MG PARTS



PEN NEEDLE PARTS (PEN NEEDLES NOT INCLUDED)



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 the 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

The HumatroPen 12 mg is an injection device intended for use with Humatrope 12 mg Cartridges. 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.

If your healthcare professional changes the prescribed cartridge size from the 12 mg Humatrope Cartridge to the 6 mg or 24 mg Humatrope Cartridge, you must get a new HumatroPen to match the new cartridge size.

Before using the HumatroPen 12 mg, make sure that you thoroughly read this 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 or your child's medical condition, or its treatment. If you are having problems using the HumatroPen 12 mg, call 1-800-545-5979.

IMPORTANT INFORMATION ABOUT THE HUMATROPEN 12 MG

- Where you see  in 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.
- 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. This is important to ensure the correct dose of Humatrope is given.
- DO NOT** use the Humatrope Cartridge past the expiration date.
- Follow Section 2 **ONLY** to set up a new Cartridge before first use.
- Section 3 of this manual should be used for every injection.
- DO NOT** transfer the contents of the Humatrope Cartridge to a syringe.
- DO NOT SHARE** the HumatroPen 12 mg or Pen Needles.
- 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 suitable for use with your HumatroPen 12 mg.
- Ask your healthcare professional what Needle gauge and length is best to use.
- Follow your healthcare professional's instructions on safe handling of needles.

Must a new Needle be used for each injection?

- Yes, a new Needle must be used for each injection.
- Remove the Needle immediately after each injection. Use a new Needle for each injection. This will help minimize the risk of infection, prevent leakage of Humatrope, keep out air bubbles, and reduce Needle clogs.

How do I throw away used Needles?

- Throw away used Needles in a puncture-proof container. Follow your healthcare professional's instructions on how to do this safely.

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.
- DO NOT SOAK** or immerse the Pen in liquid.
- DO NOT APPLY** oil or any other lubricant.

Storage

- 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 36°F to 46°F (+2°C and +8°C). **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

The HumatroPen 12 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 HumatroPen 12 mg is needed, or when the Pen has been used for 3 years.

Please see the accompanying complete Humatrope Patient Information Sheet. For additional information, call 1-800-545-5979 or visit www.humatrope.com

SECTION 2

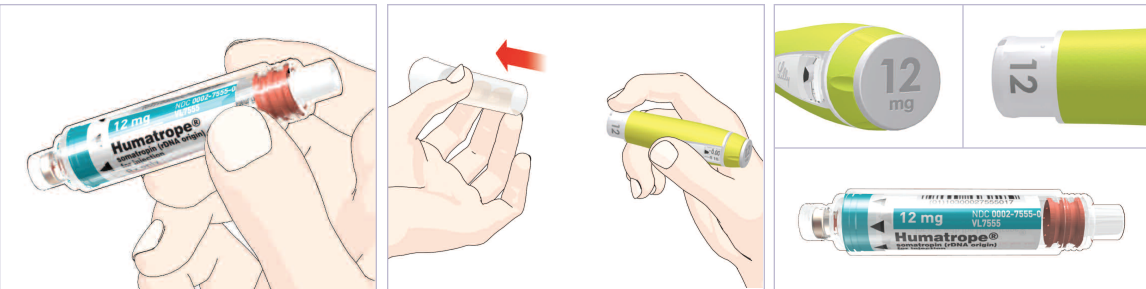
Read and follow the directions in this section only after you have read Section 1.

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

NOTE

DO NOT USE the Cartridge past the expiration date.

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

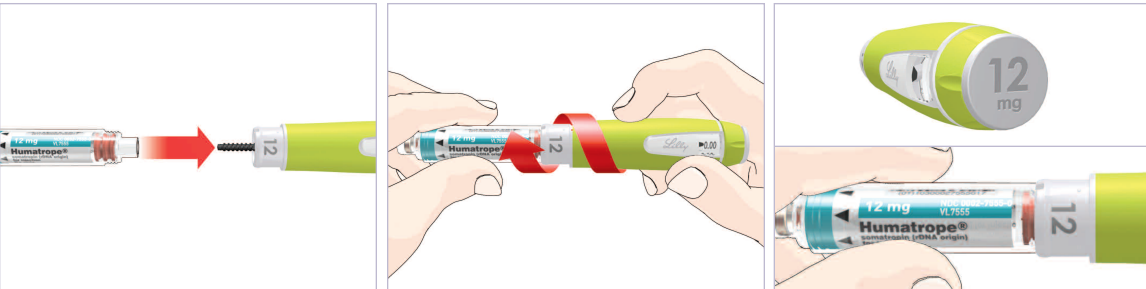
Pull off the Pen Cap.

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

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.

NOTE

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

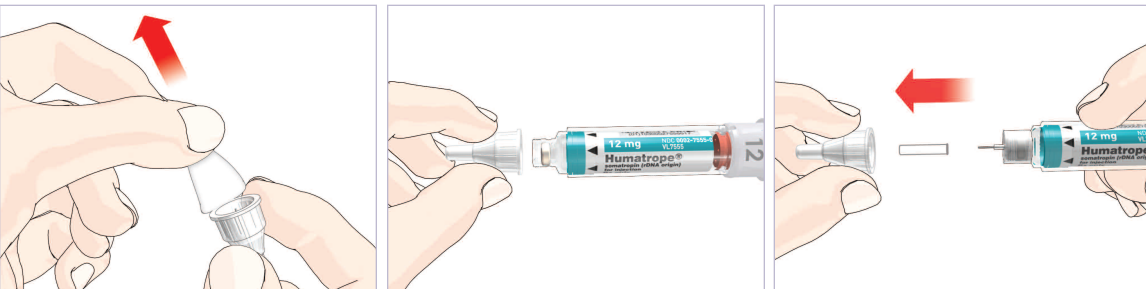
Push the White Tip of a reconstituted Cartridge into the Pen Body. Screw the 12 mg Pen Body onto the Cartridge until it is secure.

NOTE

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

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

STEP C - ATTACH THE NEEDLE

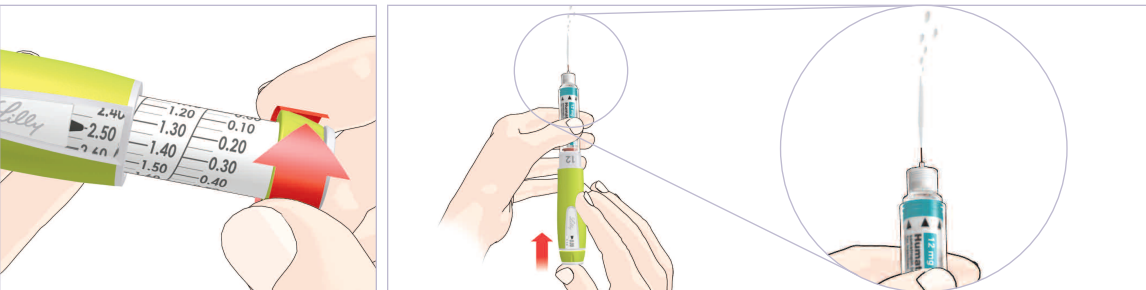


Remove the Paper Tab from the end of the Outer Cap.

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 the 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 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.

STEP E - CONTINUE ON TO DAILY USE

- DO NOT REPEAT** Cartridge Setup before each dose.
- 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.

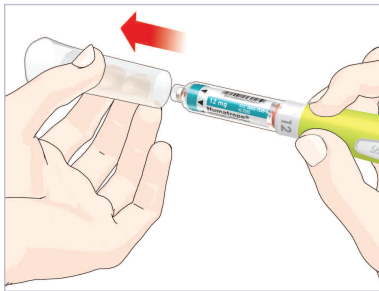


SECTION 3

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

DAILY USE

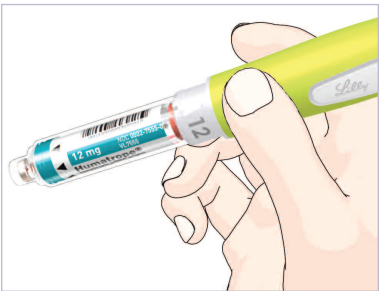
STEP 1 - CHECK THE PEN



Pull off the Pen Cap.

NOTE

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

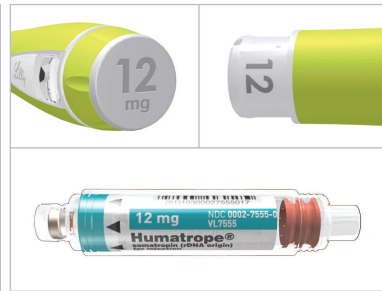


Be sure to check the Cartridge:

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

NOTE

DO NOT USE the Cartridge past the expiration date.



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

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.

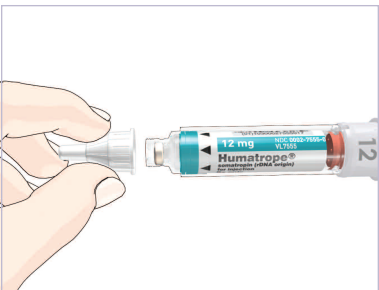
STEP 2 - ATTACH THE NEEDLE



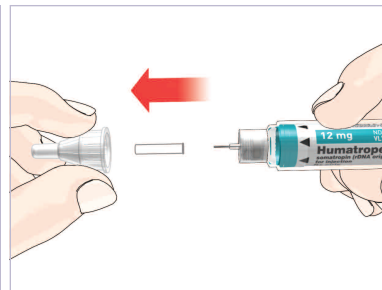
Remove the Paper Tab from the end of the Outer Cap.

NOTE

Hidden Needle Cover is available separately from the HumatroPen 12 mg Cartridge Kit. Refer to the Hidden Needle Cover user manual for instructions.



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.

STEP 3 - DIAL AND INJECT THE DOSE

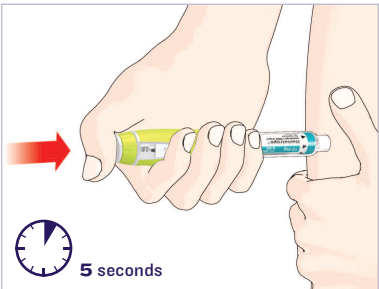


Turn the Dose Knob to desired dose.

NOTE

0.50 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, then slowly and firmly push the Injection Button until it stops moving.

Continue to hold 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 the complete dose was received.



NOTE

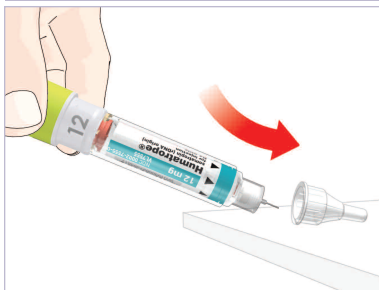
It is possible to set a dose larger than the amount of Humatrope left in the Cartridge.

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 that **WAS NOT** delivered.

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



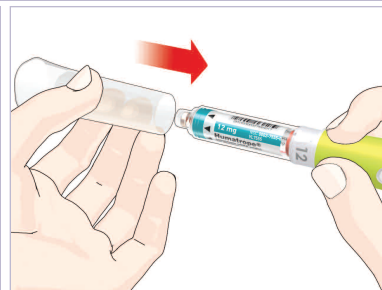
Carefully replace the Outer Cap as instructed by your healthcare professional.

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.



Remove the capped Needle by turning counter-clockwise. Throw away as directed by your healthcare professional.



Replace the Pen Cap.

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 I of this user manual for more information.)

When it is time for the 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 performed 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 12 mg and 12 mg Cartridge 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. This is important to ensure the correct dose of Humatrope is given.
- 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.

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.
- A small air bubble is normal. It will not cause any harm 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 the 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 that **WAS NOT** delivered. 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:
 - The full dose may not have been delivered. **DO NOT INJECT** another dose. Consult with your healthcare professional for assistance.
 - To prevent this, for the next dose, firmly push and hold the Injection Button in and slowly count to five (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.

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

CE
0344

Authorized Representative in the EU:
Eli Lilly and Company Ltd.
Erl Wood Manor, Windlesham, Surrey
GU20 6PH, UK

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