Instructions for Use HUMATROPE® (HU-ma-trope) (somatropin) For injection, for subcutaneous use

Single-Patient-Use Cartridge Kit

HUMATROPE cartridges are only to be used with HumatroPen® injection devices.

Read this Instructions for Use before you start using HUMATROPE Cartridge Kit and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your or your child's medical condition or treatment.

Your healthcare provider should show you how to prepare, mix, measure, and inject HUMATROPE the right way before you use it for the first time. Ask your healthcare provider if you have any questions.

How should I store HUMATROPE?

- Store HUMATROPE in the refrigerator between 36°F to 46°F (2°C to 8°C) before and after mixing.
- Do not freeze.
- Store HUMATROPE in the original carton to protect from light.
- HUMATROPE that has been mixed and is in liquid form must be used within 28 days. Throw away any mixed HUMATROPE left over after 28 days.
- Before giving an injection, check the expiration date on the Cartridge. Do not use the Cartridge if it has expired (See Figure A).

Important:

- HUMATROPE Cartridges should not be used if you are allergic to metacresol or glycerin.
- The HUMATROPE Cartridge is not recommended for use by blind or visually impaired individuals without the help of a sighted individual trained on how to use it.

HUMATROPE Cartridge Kit (See Figure A)

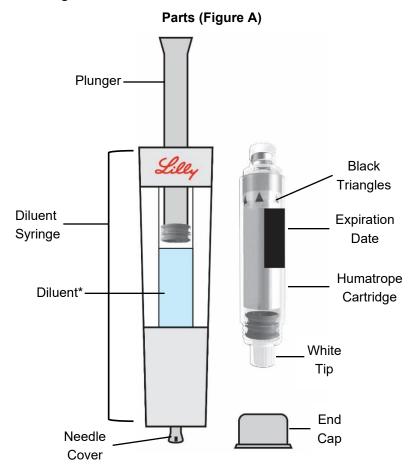
- 1 Cartridge with 6 mg, 12 mg, or 24 mg of powdered HUMATROPE
- 1 prefilled syringe with Diluent (the liquid used to mix the powdered HUMATROPE)

Note: There are 3 strengths of HUMATROPE Cartridges that have different amounts of HUMATROPE (6 mg, 12 mg, or 24 mg). Make sure that you have the Cartridge that your healthcare provider prescribed.

Mixing the HUMATROPE in the Cartridge

Only use the prefilled Diluent Syringe that comes with your HUMATROPE Cartridge Kit to mix the HUMATROPE in the Cartridge. **Do not** use the diluent that comes in the HUMATROPE vial box, or any other liquid.

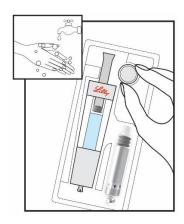
HUMATROPE Cartridge Kit mixing Instructions



Only use a HUMATROPE Cartridge Kit to prepare the HUMATROPE Cartridge.

*Note: The liquid (Diluent) should be clear, colorless, and free of particles and is shown as blue in the figure (See Figure A).

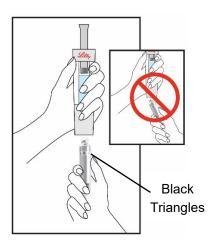
Preparing Your New HUMATROPE Cartridge



Start by thoroughly washing your hands.

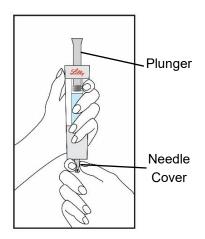
Remove all contents from the tray.

Note: The HUMATROPE Cartridge is made for left or right handed use so you may handle it the way that is most comfortable for you.

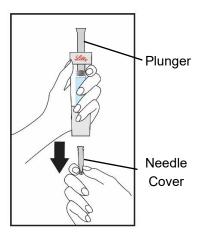


Hold the Cartridge, with the black triangles **up** toward the Diluent Syringe. Make sure the Cartridge and Diluent Syringe are facing each other in a straight line.

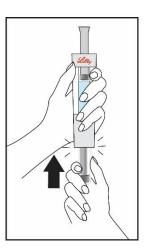
Do not insert the Cartridge at an angle.



Hold the gray needle cover at the bottom of the Diluent Syringe.



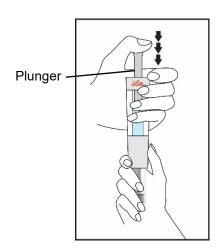
Pull the needle cover straight down to remove from the Diluent Syringe and throw it away. Do not push the plunger yet. It is okay if a drop of Diluent is seen. You do not have to release air from the Diluent Syringe.



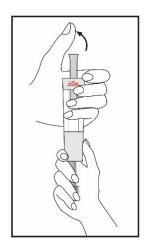
Push the Cartridge straight into the Diluent Syringe until it stops and the black triangles **are covered** inside the Diluent Syringe.

You may hear or feel a click.

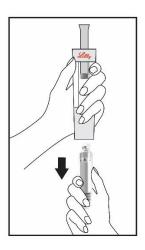
Do not twist the Cartridge.



Hold the Diluent Syringe and the Cartridge together with **both hands**. Push and release the plunger 2 or 3 times until the Diluent is in the Cartridge.



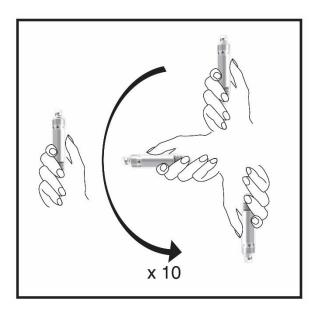
Remove your thumb from the plunger and check that the Diluent Syringe is empty. It is normal for small drops of Diluent to remain in the Diluent Syringe.



With your thumb off the plunger, pull the Cartridge away from the Diluent Syringe.



Place the end cap on a hard, flat surface. Push the Diluent Syringe onto the end cap and throw away the Diluent Syringe right away as instructed by your healthcare provider.



Mix the medicine in the Cartridge by gently moving it in an up and down motion 10 times. Then let the Cartridge sit for 3 minutes.

Do not shake.



Check the HUMATROPE liquid, it should be clear.

If the liquid is clear, your Cartridge is now prepared and ready to be attached to your HumatroPen (See the Instructions for Use for HumatroPen 6 mg, 12 mg or 24 mg).

If the liquid is cloudy or contains particles, gently mix the medicine in the Cartridge 10 more times. Let the Cartridge sit for 5 more minutes. If the liquid still remains cloudy or contains particles, **do not** use the Cartridge. Contact your healthcare provider or call Lilly at 1-800-545-5979 or go to www.humatrope.com.

If you have questions about preparing your HUMATROPE Cartridge, you should contact your healthcare provider.

Talk to your healthcare provider about the right way to use your HUMATROPE Cartridge Kit and HumatroPen injection device, the right sites to inject HUMATROPE, and how to rotate your injection sites.

Disposing of used Diluent Syringes:

- Put your used Diluent Syringes in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and syringes 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. Do not reuse or share your needles or syringes with other people. 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.

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

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