Instructions for Use
HUMATROPE® (HU-ma-trope)
(somatropin) for injection
Vial Kit

Read this Instructions for Use before you start using HUMATROPE and each time you get a new HUMATROPE vial. 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.

Do not share your syringes or needles with anyone else, even if the needle has been changed. You may give other people a serious infection or get a serious infection from them.

HUMATROPE is not recommended for use by blind or visually impaired individuals without the help of a sighted individual trained on how to use it.

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.
- Protect HUMATROPE from light during storage.
- Do not leave the HUMATROPE vial out of the refrigerator for more than 30 minutes a day.
- HUMATROPE that has been mixed with Sterile Diluent for Humatrope and is in liquid form, should be used within 14 days. Throw away any mixed HUMATROPE left over after 14 days.

You will need the following supplies to mix your HUMATROPE and give your injection (Figures A and B):
- 2 alcohol swabs
- 1 cotton swab or gauze pad
- 2 sterile syringes (as recommended by your healthcare provider)
- 2 sterile needles (as recommended by your healthcare provider)
- 1 Sterile Diluent for HUMATROPE vial (provided in Humatrope Kit)
- 1 HUMATROPE vial (provided in Humatrope Kit)
- 1 sharps container for throwing away used needles and syringes. See “Disposing of used needles and syringes” at the end of these instructions.

Before mixing your HUMATROPE, check the expiration date on the vial labels (See Figure A). Do not use any vial that has expired. Contact your healthcare provider or call Lilly at 1-800-545-5979 if either vial has expired.
Mixing the Vial of HUMATROPE:
- Only mix HUMATROPE with the Diluent for HUMATROPE that comes in the package.
- **Do not** use other solutions for mixing HUMATROPE unless instructed to do so by your healthcare provider.
- Your healthcare provider will also tell you what size syringe and needle to use and how much Diluent to add to the vial of HUMATROPE.

_Wash your hands with soap and water._

**Step 1.**
- Remove and throw away (discard) plastic caps from the tops of the vials of HUMATROPE and Diluent for HUMATROPE. Wipe tops of both vials with an alcohol swab (See Figure C).

**Step 2.**
- Remove outer wrapping from 1 syringe (See Figure D).
Step 3.
- Remove outer wrapping from 1 needle. Place needle on top of syringe and turn until it is tight and firmly attached (See Figure E).

Step 4.
- Remove needle cover by pulling straight off (See Figure F).

Step 5.
- Pull back on the syringe plunger to draw up an amount of air equal to the amount of Diluent your healthcare provider has prescribed (See Figure G).
Step 6.
- Insert the needle in the center of the stopper of the **Diluent for HUMATROPE vial** (See Figure H). Push down on the syringe plunger to insert air into the vial.

![Figure H](image)

Figure H

Step 7.
- Hold the Diluent vial upside down, making sure the needle tip remains in solution.
- Slowly pull back on the syringe plunger until the tip of the plunger reaches the line for the amount of Diluent your healthcare provider has prescribed (See Figure I).
- If there are air bubbles, tap the syringe gently a few times to let any air bubbles rise to the top. Slowly push the plunger up to remove the air bubbles.
- If you push the Diluent back into the vial to remove the air bubbles, slowly pull back on the plunger to draw the correct amount of Diluent your healthcare provider prescribed.

![Figure I](image)

Figure I

Step 8.
- Turn the vial back upright, while holding the barrel, and slowly pull the needle out of the Diluent vial (See Figure J).

![Figure J](image)

Figure J

Step 9.
- Insert the needle into the vial of **HUMATROPE** and gently aim the needle tip toward the wall of the vial.
- Slowly push down on the syringe plunger to inject the Diluent by aiming the stream of liquid against the wall of the vial (See Figure K).
- **Do not** aim the needle tip at the white powder at the bottom of the vial.

![Figure K](image)

**Step 10.**
- Remove the needle from the vial.
- Throw away the syringe with the needle attached. See “Disposing of used needles and syringes” at the end of these instructions.

**Step 11.**
- Swirl the HUMATROPE vial in a gentle circular motion until the powder is completely dissolved into liquid (See Figure L).
- **Do not** shake.

![Figure L](image)

**Step 12.**
- Write the date that you mixed the HUMATROPE on the vial label, and throw away the unused Diluent. You will use the mixed vial of HUMATROPE for each injection.
- Keep the mixed vial of HUMATROPE in the refrigerator.
- Protect HUMATROPE from light during storage.
- **Throw away the mixed vial of HUMATROPE after 14 days** even if there is still medicine in the vial.

**Preparing to give your Injection:**

**Step 13.**
- After mixing and before each injection, check the liquid in the HUMATROPE vial. The liquid should look clear, colorless, and free of particles. **Do not** use mixed HUMATROPE if it is cloudy or contains particles. Contact your healthcare provider or call Lilly at 1-800-545-5979 or go to www.humatrope.com.
- Take the vial of HUMATROPE out of the refrigerator and let it sit for **10 minutes before injecting** to allow it to reach room temperature. Injecting medicine that is cold can cause discomfort.

**Step 14.**
- Before each injection, clean the rubber stopper of the mixed HUMATROPE vial with an alcohol swab.

**Step 15.**
- When you are ready to give your injection use a new sterile syringe.
- Remove outer wrapping from 1 syringe.

**Step 16.**
- Use a new sterile needle.
- Remove outer wrapping from 1 needle. Your healthcare provider will tell you the right size needle to use. Place needle on top of the syringe and turn until it is tight and firmly attached.

**Step 17.**
- Remove the needle cover.

**Step 18.**
- Pull back on the syringe plunger to draw up an amount of air equal to the amount of HUMATROPE your healthcare provider has prescribed.

**Step 19.**
- Insert the needle into your vial of mixed HUMATROPE and inject the air into the vial.

**Step 20.**
- Hold the vial upside down making sure to keep the needle tip in the solution and withdraw your correct dose. Make sure that no air bubbles are in the syringe.

**Injecting HUMATROPE:**

**Step 21.**
- Choose your injection site. Your healthcare provider should show you the best areas to give your injection. Choose a different injection site each day.
- Injections can be given under the skin (subcutaneously) in the following areas (See Figure M):
  - Abdomen: above, below, or either side of the belly button (navel)
  - Front of the upper thighs
  - Upper, outer buttocks
  - Back of the arms above the elbow and below the shoulder

![Figure M](image)

**Step 22.**
- Wipe the area well with an alcohol swab. Use a circular motion and work outward from the inside of the circle (See Figure N).
Step 23.
- With the thumb and forefinger of one hand, pinch up a fold of skin (See Figure O).

Figure O

Step 24.
- Holding the syringe at a 90-degree angle to the injection site or as recommended by your healthcare provider, quickly insert the needle all the way into the pinched area of skin (See Figure P).

Figure P

Step 25.
- After the needle is inserted, release the pinched skin. Slowly inject the solution by gently pressing the plunger all the way down until the syringe is empty (See Figure Q).

Figure Q

Step 26.
- Remove the needle quickly, and apply pressure over the injection site with a dry gauze pad or cotton swab. Rub the injection site for several seconds.

Step 27.
- Throw away used needles and syringes in a sharps container. See “Disposing of used needles and syringes” at the end of these instructions.
Step 28.
- Return mixed vial of HUMATROPE to the refrigerator and use within 14 days.
- Protect HUMATROPE from light during storage.

Disposing of used needles and syringes:
- Put your used needles and 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](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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