

TEV-TROPIN[®]
[somatropin (rDNA origin) for injection]
5 mg & 10 mg

TEV-TROPIN[®]
(somatropin for injection)
Information for the Patient or Parent
Read all instructions before proceeding.

Do not mix (reconstitute) the drug or inject it until you have been thoroughly trained in the proper techniques by your doctor. Use sterile techniques as instructed by your doctor. The first injection of TEV-TROPIN should be given under the supervision of your doctor. Properly discard syringes and/or needles after each use.

PREPARATION

Your GROWTH HORMONE is supplied in a powder form that must be prepared for injection by mixing it with a *diluent* (a liquid, either Bacteriostatic 0.9% Sodium Chloride Injection, USP [5 mg vial] or Bacteriostatic Water for Injection with 0.33% Metacresol [10 mg vial]) prior to use. Only use the specific *diluent* that is supplied in the carton containing your GROWTH HORMONE. Once you have reconstituted your GROWTH HORMONE with the *diluent*, it is ready for injection. Your doctor will prescribe the exact amount of diluent and tell you the size of the syringe and needle to use.

Note: The *diluents* are different for the 5 mg and 10 mg vials. Do not interchange the *diluents*.

TEV-TROPIN should be kept refrigerated (36° to 46°F [2° to 8°C]) before and after reconstitution. Do not freeze.

TEV-TROPIN 5 mg is supplied with a vial of liquid containing Bacteriostatic 0.9% Sodium Chloride Injection, USP (5 mL). After TEV-TROPIN 5mg vial is mixed with the *diluent*, the vial should be used within 14 days.

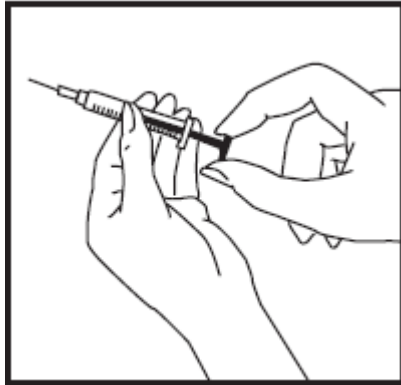
TEV-TROPIN 10 mg is supplied with a syringe of liquid containing vial Bacteriostatic Water for Injection with 0.33% Metacresol as a preservative. After TEV-TROPIN 10 mg vial is mixed with the *diluent*, the vial should be used within 28 days.

Before preparing your medication, be sure to wash your hands thoroughly with soap and water. This will help prevent infection.

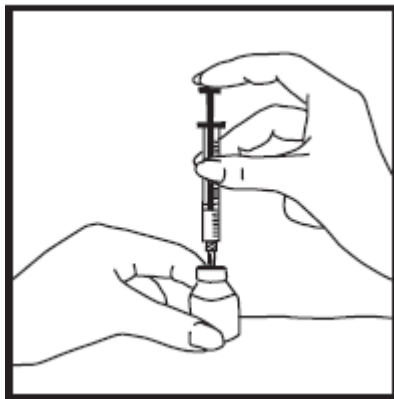
Preparing TEV-TROPIN 5 mg:

(1) Remove the hard plastic cap from the top of the *diluent* vial by gently pushing up on the edge of the cap. Do not remove the rubber stopper. Using an alcohol swab, wipe off the top of the *diluent* bottle. After cleansing, do not touch the rubber stopper.

(2) Carefully remove the needle cap from the syringe, taking care not to touch the needle. Do not discard the needle cap. Hold the barrel of the syringe with one hand and pull back on the plunger with the other, until you have drawn up the amount of air that is the same as the amount of diluent your doctor has ordered.



(3) Insert the needle into the *diluent* vial through the center of the cleansed rubber stopper. Push down on the plunger until all the air is released into the vial.



(4) Holding the vial with one hand, carefully turn it upside down making sure the syringe needle stays in the vial. The tip of the needle should be below the surface of the *diluent*. With your other hand, gently pull back the plunger until the amount of *diluent* your doctor has prescribed is in the syringe. Once the syringe is correctly filled with the *diluent*, remove the syringe and needle



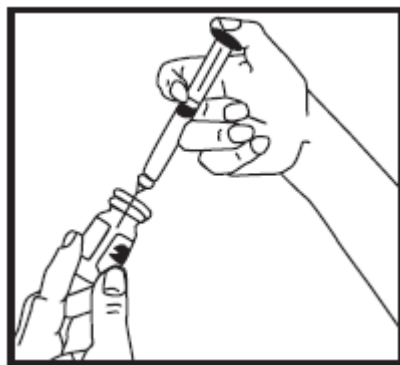
Preparing TEV-TROPIN 10mg:

(1) Remove the syringe tip cap from the top of the pre-filled *diluent* syringe and attach the 25G mixing needle that is supplied in the carton.

DILUTING TEV-TROPIN

Remove the hard plastic top of the GROWTH HORMONE vial. Cleanse the top of the GROWTH HORMONE vial with an alcohol swab. Remove the needle cap from the syringe filled with *diluent* and insert the needle into the center of the rubber stopper on the GROWTH HORMONE vial from the vial and recap the needle.

(1) Point the needle toward the side of the vial and slowly push the plunger so that the *diluent* squirts onto the side of the vial, not directly onto the powder. When all the *diluent* is in the GROWTH HORMONE vial, remove the needle from the vial, recap the needle and discard the syringe.



(2) To mix the GROWTH HORMONE, hold the vial between your hands and gently roll it until the mixture is clear. NEVER SHAKE THE VIAL! Sometimes the vial may need to sit a few seconds before the mixture becomes clear. Do not use the mixture in the vial if it remains cloudy or you see particles floating in the mixture. If air bubbles appear, let the GROWTH HORMONE sit for a while until they disappear.

Write the date you reconstitute the GROWTH HORMONE on the vial label. The 5 mg vial must be used within 14 days whereas the 10 mg vial must be used within 28 days. Store reconstituted GROWTH HORMONE along with all unopened vials of the GROWTH HORMONE in a safe, clean place in the refrigerator. Do not freeze.

INJECTION

To prepare to give an injection of GROWTH HORMONE, begin by thoroughly washing your hands with soap and water. Check that the vial of GROWTH HORMONE you are using is clear and that the date of reconstitution is within 14 days (5 mg) or 28 days (10mg).

(1) Cleanse the top of the GROWTH HORMONE vial with an alcohol swab. After cleansing, do not touch the rubber stopper. Remove the needle cap from the syringe

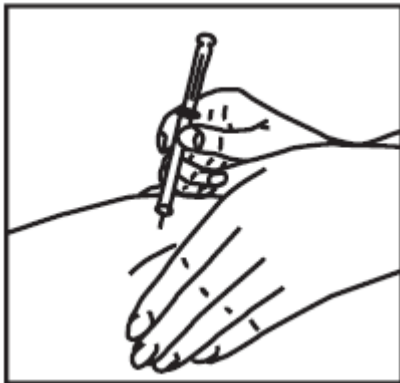
and insert the needle into the center of the rubber stopper on the GROWTH HORMONE vial. Gently pull back the plunger until the amount of GROWTH HORMONE solution your doctor has prescribed is in the syringe.

Once the needle is correctly filled with the solution, remove the needle from the vial. Recap the needle. If you are not experienced with filling a syringe, ask your doctor for a demonstration.

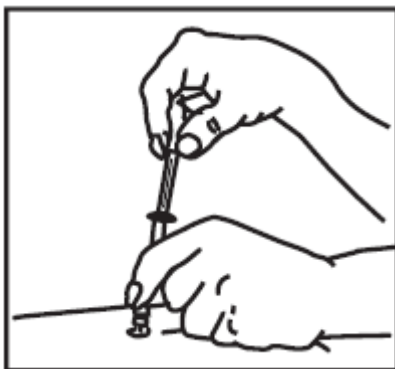
(2) Choose a site for your injection. Clean the injection site with an alcohol swab, using a circular pattern, and work from the injection site outward about 2 inches. Allow the alcohol to dry before giving the injection.

(3) Check that the correct dose is in the syringe and remove the needle cap. Hold the syringe the way you hold a pencil.

(4) With your free hand, pinch the cleansed skin between your fingers and quickly insert the needle into the skin at a 45° - 90° angle with a quick, firm wrist motion.



(5) Holding the syringe in place, pull back a little on the plunger and check to see if any blood flows into the syringe (vessel check). If you see blood in the syringe, remove the needle and syringe and discard. You will then need to prepare a new syringe for injection.



(6) If, during the vessel check, you see no blood, then slowly push down plunger until the syringe is completely empty.

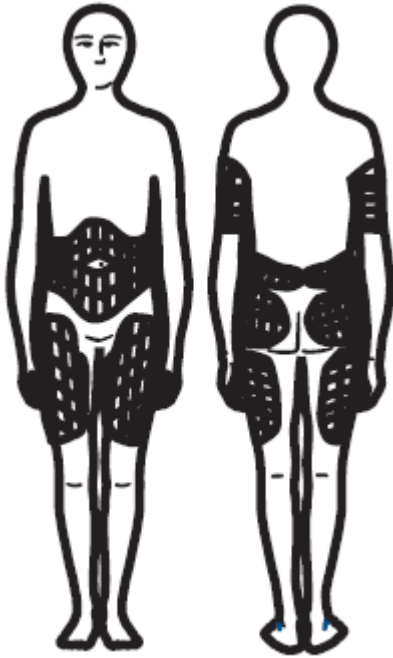
(7) Quickly remove the needle from the skin and apply pressure to the injection site with a dry sterile gauze pad or cotton ball. A drop of blood may appear. Apply a small bandage if desired.

(8) Dispose of needle and syringe in a proper container identified by your physician or pharmacist. Never dispose of needles and syringes in your household trash.

INJECTION SITES

There are different sites you can use for your injections.

These sites should be rotated.



If you notice any of the following signs, contact your physician:

- A lump, bruise or redness at the injection site that doesn't go away.
- Any sign of infection at the injection site (pus, redness, heat or persistent pain).
- Severe, sharp pain or persistent ache at injection site.
- Rash at injection site.

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