

SOMAVERT[®]

pegvisomant for injection

PATIENT INFORMATION

SOMAVERT (SOM-ah-vert) (pegvisomant for injection)

Read the patient information that comes with SOMAVERT before you start using it and each time you get a refill, because new information may have been added. The information in this leaflet does not take the place of talking to your doctor about your medical condition or your treatment. If there is anything you do not understand in the instructions, or cannot do, call the toll-free number listed at the end of this leaflet.

What is SOMAVERT?

SOMAVERT is a medicine used to treat patients who have acromegaly. Acromegaly is a disease caused by the body making too much growth hormone.

Who should not use SOMAVERT?

Do not use SOMAVERT if you are allergic to SOMAVERT or any of its ingredients. The active ingredient is pegvisomant, which includes polyethylene glycol. The inactive ingredients are glycine, mannitol, sodium phosphate dibasic anhydrous, and sodium phosphate monobasic monohydrate. **The stopper on the vial of SOMAVERT contains latex.**

SOMAVERT has not been studied in children.

Tell your doctor if you:

- are pregnant or plan to become pregnant. We do not know if SOMAVERT can harm your unborn baby. You and your doctor will have to decide if SOMAVERT is right for you.
- are breast-feeding. We do not know if SOMAVERT passes into your milk or if it can harm your baby.
- have diabetes.
- have or had liver problems.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Be sure to tell your doctor if you use:

- insulin or other medicines (oral hypoglycemic medicines) for diabetes. The doses of these medicines may need to be changed if you use SOMAVERT.

- narcotic painkillers (opioid medicines). Your dose of SOMAVERT may need to be changed if you use any of these medicines.

How should I use SOMAVERT?

- Read the detailed “Instructions for Use” at the end of this leaflet before using SOMAVERT.
- SOMAVERT is given once a day as an injection under the skin (subcutaneous).
- Your first dose, called a loading dose, will be given to you by your health care professional.
- Your health care professional will teach you or your caregiver how to inject SOMAVERT.
- If you forget to give yourself an injection of SOMAVERT, skip that dose. Get back on your schedule the next day. Do **not** inject a double dose to make up for a forgotten injection.
- If there is anything you do not understand in the instructions, or cannot do, call your health care professional or the toll-free number listed at the end of this leaflet.

What are the possible side effects of SOMAVERT?

Some patients who have used SOMAVERT have developed liver problems. Stop SOMAVERT right away and call your doctor if you get any of the following symptoms:

- your skin or the white part of your eyes turns yellow (jaundice).
- your urine turns dark.
- your bowel movements (stools) turn light in color.
- you do not feel like eating for several days.
- you feel sick to your stomach (nausea).
- you have unexplained tiredness.
- you have pain in the stomach area (abdomen).

Your doctor may do blood tests before and during your treatment with SOMAVERT to check that your liver is working correctly and to see how you are responding to SOMAVERT. Your dose of SOMAVERT may be changed based on these test results.

The most common side effects with SOMAVERT are pain, infection, reaction at the site of injection, flu symptoms, nausea, and diarrhea. These are not all of the possible side effects of SOMAVERT. For more information, ask your doctor or pharmacist.

INSTRUCTIONS FOR USE

Your health care professional should teach you how to mix and inject SOMAVERT.

SOMAVERT is packaged in dry powdered form. Before you use SOMAVERT, it must first be mixed with a liquid called a diluent. The diluent is in the same packaging with the medicine. It is called Sterile Water for Injection, USP. Use only this diluent for mixing SOMAVERT. Do not use any other liquid to mix the medicine.

Use only one dose from each vial (small bottle) of SOMAVERT.

Storage

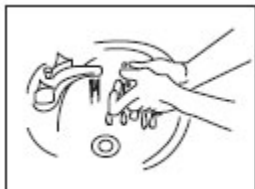
Before you mix the powder and the liquid, store the package of SOMAVERT in a refrigerator (36 to 46°F). Do not freeze.

After mixing the powder and liquid, you may keep the mixed medicine at room temperature inside the vial or the syringe, but you must inject the mixed SOMAVERT within 6 hours. If you have not used the mixed medicine within 6 hours, throw it away.

Getting Started

Remove 1 package of SOMAVERT from the refrigerator. Let it warm up to room temperature for about 10 minutes while you get ready to prepare your injection.

1. Wash your hands with soap and warm water. Dry your hands well.



2. Gather the necessary supplies:

- The package of SOMAVERT that is now at room temperature, which contains 1 vial of powder (SOMAVERT) and 1 vial of liquid (diluent called Sterile Water for Injection, USP)
- One 1-cc syringe, with a 18- to 21-gauge, 1-inch or longer needle (this will be the “diluent syringe”)
- One 1-cc insulin syringe, with a 27- to 30-gauge, 1/2-inch needle that is permanently attached to the syringe (this is the syringe you will use for the injection)
- Alcohol or antiseptic swabs
- Proper container for throwing away used needles.



Mixing SOMAVERT

3. Remove the protective plastic caps from the tops of both vials (medicine and diluent). Do not touch the rubber vial stoppers. The stoppers are clean. If the stoppers are

touched by anything, you must clean them with an antiseptic or alcohol swab before use.

Carefully remove the cap from the syringe with the larger needle and set the cap aside. This is the diluent syringe.



4. Pull the plunger of the diluent syringe out to the 1-cc mark. With one hand, firmly hold the vial of diluent. With the other hand, push the needle of the diluent syringe straight through the center of the rubber stopper and deep into the vial. Gently push the plunger in until the air is injected into the vial.



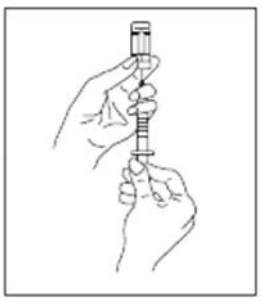
5. Firmly hold the diluent vial and syringe together, with the needle still deeply inserted into the vial. Carefully turn the vial and syringe together upside down. Bring them to eye level.



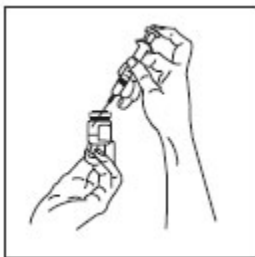
6. Slide one hand carefully down the diluent vial so that with your thumb and forefinger you can firmly hold the neck of the vial, and with your other fingers you can hold the upper part of the syringe. With the other hand, slowly pull the syringe plunger out to slightly past the 1-cc mark.

Check the syringe for air bubbles. If you see bubbles, tap the syringe barrel until the bubbles rise to the top of the syringe. Carefully push the plunger in to push only the air bubbles back into the vial. Recheck that 1 cc of diluent remains in the syringe.

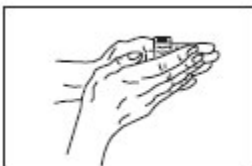
Then, pull the needle out of the vial. The vial should still have a lot of diluent in it. Do not use the leftover diluent.



7. Push the needle of the diluent syringe straight through the stopper of the vial of SOMAVERT (the one with the powder). Tilt the syringe to the side and gently push the plunger in to inject the diluent down the inner side of the vial of SOMAVERT. Be sure the diluent does not fall directly on the powder, but flows down the inside wall of the vial. When the syringe is empty, pull the needle out from the vial. Throw away the diluent vial with the leftover liquid in it, and the diluent syringe and needle as directed by your health care professional. To help prevent accidental injury, recap the needle only if taught to do so by your health care professional, and in the way you were told to do so by your health care professional.



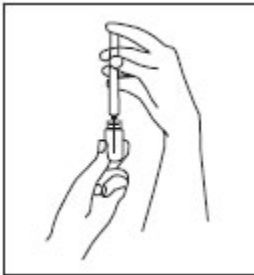
8. Hold the vial of SOMAVERT upright between your hands and gently roll it to dissolve the powder. **Do not shake the vial. Shaking may destroy the medicine.** The medicine mixture should be clear after the powder is dissolved. Do not inject the mixture if it looks cloudy or hazy, slightly colored, or if solid particles are visible. Tell your pharmacist and ask for a replacement vial. Do not throw the vial away because the pharmacist may ask that you return it. **Inject SOMAVERT within 6 hours of mixing it. If you wait more than 6 hours, you must throw away the mixture without injecting it.**



Preparing the Injection

9. Clean the rubber stopper of the vial of SOMAVERT with an antiseptic or alcohol swab. Carefully remove the cap from the insulin syringe (the one with the permanently attached needle) and set the cap aside. Pull the syringe plunger out to the 1-cc mark. With one hand, firmly hold the vial. With the other hand, push the needle straight through the center of the rubber stopper and deep into the vial. Gently push the plunger in until the air is injected into the vial.

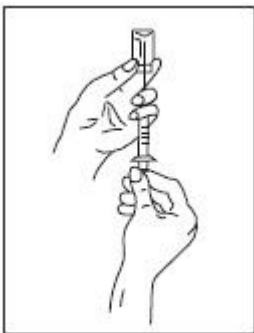
Firmly hold the vial and syringe together, with the needle still deeply inserted into the vial. Carefully turn the vial and syringe together upside down. Bring them to eye level.



10. As before, slide one hand carefully down the vial so that with your thumb and forefinger you can firmly hold the neck of the vial, and with your other fingers you can hold the upper part of the syringe. With the other hand, slowly pull the syringe plunger out to withdraw the full contents of the vial (1 cc). To keep the needle tip within the mixture, you may have to pull the needle out of the stopper slowly as you draw out the liquid.

Check the syringe for air bubbles. If you see bubbles, tap the syringe barrel until the bubbles rise to the top of the syringe. Carefully push the plunger in to push only the air bubbles back into the vial. Recheck that 1 cc of the mixture remains in the syringe. Then pull the needle out of the vial.

Recap the needle as directed by your health care professional to help prevent accidental injury while preparing the site for injection.



Giving the Injection

Subcutaneous (under the skin) injection sites may include the upper arm, upper thigh, abdomen (stomach area) and buttocks. Choose the injection site from one of the areas identified by your health care professional.

Choose a different injection site each day so lumps do not develop. Keep a record of each day's injection site as you take your daily dose of SOMAVERT. Do not use an area that has a rash or broken skin, or is bruised or lumpy.

11. Prepare the injection site area as taught by your health care professional. If you clean the site with an antiseptic or alcohol, let the skin dry before injecting the medicine. Uncap the needle if it was recapped.



12. With one hand, gently pinch up the skin at the site of injection. Hold the insulin syringe with the other hand. In a single, smooth motion, push the needle completely into the skin straight down, at a 90-degree angle.



13. Be sure to keep the needle all the way into the skin while you slowly push the syringe plunger in until the barrel is empty.

Release the pinched skin and pull the needle straight out.



14. Do not rub the injection area. A small amount of bleeding may occur. If necessary, apply a clean, dry cotton pad over the area and press gently for 1 or 2 minutes, or until the bleeding has stopped.



15. Safely throw away needles and syringes as directed by your health care professional, according to local health regulations.

Your health care professional or pharmacist can give you information about the right way to throw away the needles and syringes. Be sure to store and throw away your treatment materials in a way that lowers danger to others.



General information about the safe and effective use of SOMAVERT

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use SOMAVERT for a condition for which it was not prescribed. Do not give SOMAVERT to other people, even if they have the same symptoms you have. **Keep SOMAVERT and all medicines out of the reach of children.**

This leaflet summarizes the most important information about SOMAVERT. If you would like more information, talk with your doctor or ask your doctor or pharmacist for the information about SOMAVERT that is written for health care professionals.

Questions about how to inject SOMAVERT?

Call Pharmacia & Upjohn Company toll-free at (800) 645-1280

For more information, please visit www.Somavert.com

Rx only



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