CONSUMER INFORMATION
Product Monograph Part III

PrSOMAVERT*
pegvisomant
10 mg, 15mg, and 20 mg per vial

Pfizer Canada Inc.

Submission Control No. 082148

The Consumer Information Section (Part III) of the Product Monograph for PrSOMAVERT* has been submitted by the drug sponsor and is attached for your information.

The attached version accompanied the Notice of Compliance issued on October 17, 2005, and does not necessarily reflect the most current information for the product.

For the most up-to-date product information, please consult your health care professional.

Due to the fact that the information originated with an organization that is not subject to the *Official Languages Act*, the document may only appear in the language in which it was written. Translations of the document are the responsibility of the sponsor involved.

PART III: CONSUMER INFORMATION

^{Pr}SOMAVERT*
pegvisomant for injection

This leaflet is part III of a three-part "Product Monograph" published when SOMAVERT (pegvisomant for injection) was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SOMAVERT. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

Your doctor has prescribed **SOMAVERT** (pegvisomant for injection) for you. Read these instructions completely before using **SOMAVERT** and each time you renew your prescription, just in case anything has changed. If there is anything you do not understand or cannot do, contact your healthcare professional. These instructions do not take the place of careful discussions with your doctor.

What the medication is used for:
SOMAVERT is a medicine used to treat acromegaly, which is a disease caused when the body produces too much growth hormone.

What it does:
SOMAVERT blocks the effect of too much growth hormone and improves the symptoms of acromegaly.

When it should not be used:
You should not use this medicine if you have had an allergic reaction to **SOMAVERT** or any of its ingredients.

What the medicinal ingredient is:
The active ingredient is pegvisomant.

What the important nonmedicinal ingredients are:
None. The inactive ingredients are glycine, mannitol, sodium phosphate dibasic anhydrous, and sodium phosphate monobasic monohydrate.

What dosage forms it comes in:
SOMAVERT is supplied as a sterile powder intended for subcutaneous (under the skin) injection after reconstitution with 1 mL of Sterile Water for Injection (Ph. Eur.). It is available in single-dose vials containing 10, 15, or 20 mg of pegvisomant protein.

WARNINGS AND PRECAUTIONS

BEFORE you use SOMAVERT talk to your doctor or pharmacist if you:

- Have liver disease now, or have had liver disease in the past.
- Take insulin or anti-diabetes drugs, because the dose of these medicines may need to be changed when you use **SOMAVERT**.
- Take opioids, because the dose of **SOMAVERT** may need to be changed when you take these medicines.
- Plan to become pregnant, or if you are pregnant, might be pregnant, or do not use effective birth control.
- Plan to breast-feed, or if you are already breast-feeding.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor about all medications (prescription and non-prescription) you are using. It is especially important that your doctor know if you are taking insulin or anti-diabetes drugs and opioids.

PROPER USE OF THIS MEDICATION

SOMAVERT is intended for subcutaneous (under the skin) administration. Your first dose, called a loading dose, will be given to you by a health care professional. Following this, your health care professional will instruct you to inject **SOMAVERT** subcutaneously once a day. You and any caregiver who may give you the injections should receive individual training under the supervision of the prescribing doctor.

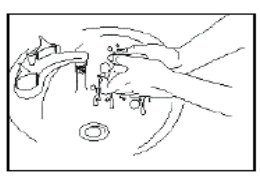
Always follow the detailed instructions that are given below (INSTRUCTIONS FOR USE) when you are preparing or injecting **SOMAVERT**. However, these instructions do not replace the individual training by a health care professional.

INSTRUCTION FOR USE
SOMAVERT is packaged in dry powdered form. Before you use **SOMAVERT**, it must first be reconstituted. This means it is mixed with a liquid called a diluent. The diluent is in the same packaging with the medicine. It is called Sterile Water for Injection, Ph. Eur. It is the only approved diluent for reconstituting **SOMAVERT**. Do not use any other liquid to reconstitute the medicine.

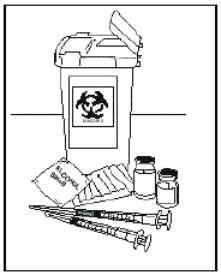
Use only one dose from each vial (small bottle) of **SOMAVERT**.

Getting Started

Remove one package of **SOMAVERT** from the refrigerator and allow it to warm up to room temperature for approximately 10 minutes while you get ready to prepare your injection.



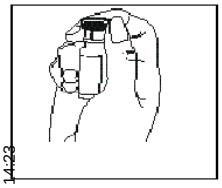
1. Wash your hands with soap and warm water. Dry your hands well.



2. Gather the necessary supplies:

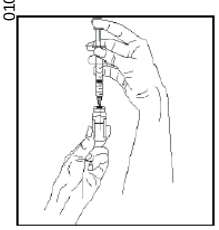
- The package of **SOMAVERT** that is now at room temperature, which contains one vial of powder (**SOMAVERT**) and one vial of liquid (Sterile Water for Injection, Ph. Eur.)
- One 1-cc syringe, with a 21-gauge, 1-inch detachable needle (this will be the "diluent syringe")
- One 1-cc insulin syringe, with a 27- to 30-gauge, ½-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.

Reconstituting SOMAVERT

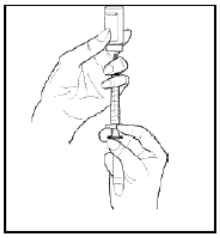


3. Remove the protective plastic caps from the tops of both vials (medicine and diluent). Take care not to touch the rubber vial stoppers. At this point, the stoppers are clean. If the stoppers are touched by anything, you must clean them with an antiseptic or alcohol swab before use.

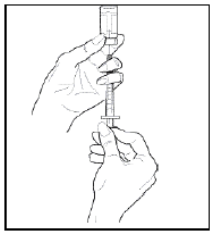
   Carefully remove the cap from the detachable needle and set the cap aside. This needle is used in the diluent syringe.



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.

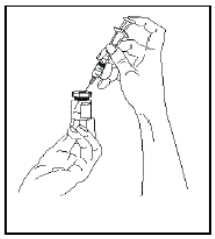


5. Firmly hold the diluent vial and syringe together, with the needle still deeply inserted into the vial. Carefully turn the vial and syringe together upside down. Bring them to eye level.

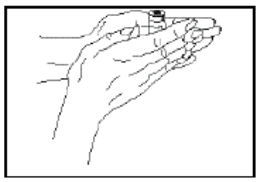


6. Slide one hand carefully down the diluent vial so that with your thumb and forefinger you can firmly hold the neck of the vial, and with your other fingers you can hold the upper part of the syringe. With the other hand, slowly pull the syringe plunger out to slightly past the 1-cc mark.

   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.**

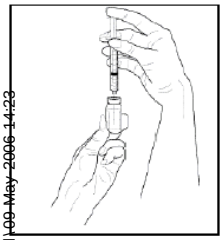


7. Push the needle of the diluent syringe straight through the stopper of the vial of **SOMAVERT** (the one with the powder). Tilt the syringe to the side and gently push the plunger in to inject the diluent down the inner side of the vial of **SOMAVERT**. Be sure the diluent does not fall directly on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



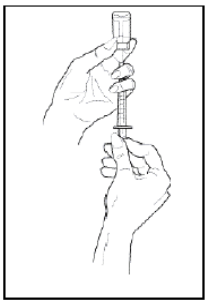
8. Hold the vial of **SOMAVERT** upright between your hands and gently roll it to dissolve the powder. **Do not shake the vial, as shaking may inactivate the medicine.** The mixture should be clear after the powder is dissolved. Do not inject the mixture if it appears cloudy or hazy, slightly colored, 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 3 hours of mixing it. If you wait more than 3 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.



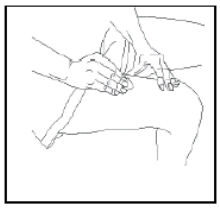
10. As before, slide one hand carefully down the vial so that with your thumb and forefinger you can firmly hold the neck of the vial, and with your other fingers you can hold the upper part of the syringe. With the other hand, slowly pull the syringe plunger out to withdraw the full contents of the 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.

11. 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.

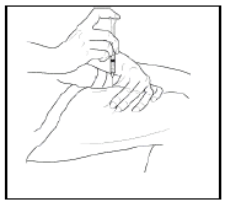
    Recap the needle as directed by your health care professional to help prevent accidental injury while preparing the site for injection.

Giving the Injection

Subcutaneous (under the skin) injection sites may include the upper arm, upper thigh, abdomen (stomach area) and buttocks. Select the injection site from one of the areas identified by your health care professional. Select a different injection site each day. It may be helpful to 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.



12. Prepare the injection site area as instructed 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.

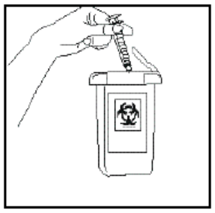


13. With one hand, gently pinch up the skin at the site of injection. Hold the insulin syringe with the other hand. In a single, smooth motion, push the needle completely into the skin straight down, at a 90-degree angle.

14. 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.

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



16. Safely throw away needles as directed by your health care professional, according to local environmental health regulations.

    Your health care professional or pharmacist can give you information about throwing away the needles correctly. Be certain to store and throw away your treatment materials in a way that reduces danger to others.

Overdose:
In cases of overdose, administration of **SOMAVERT** should be discontinued and not resumed. Contact you doctor immediately.

Missed Dose:
If you forget to give yourself an injection of **SOMAVERT**, get back on the schedule the next day. Do not inject a double dose to make up for a forgotten injection.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

SOMAVERT is generally well tolerated. The side effects are usually mild and do not last long. The following is not a complete list of side effects. Ask your doctor to tell you about the other side effects.

The most common side effects related to the use of the drug are pain, infection, reaction at the site of injection, flu symptoms, and nausea.

A small number of patients who have used **SOMAVERT** have developed liver problems. Immediately stop therapy with **SOMAVERT** and contact your doctor if you notice any of the following:

- Sudden yellowing of the skin or whites of the eyes, or darkening of the urine
- Unexplained fatigue, nausea, vomiting, or pain in the abdomen (stomach area).

Your doctor will draw some of your blood before and during treatment with **SOMAVERT** to check how you are responding to the medicine, to change the dose if necessary, and to check for potential liver problems.

This is not a complete list of side effects. For any unexpected effects while taking SOMAVERT, contact your doctor or pharmacist.

HOW TO STORE IT

Until you mix the powder and the liquid, store the package of **SOMAVERT** in a refrigerator (2 to 8°C). Protect it from freezing.

After reconstitution (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 3 hours. If you have not used the mixed medicine within 3 hours, throw it away.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345
toll-free fax 866-678-6789
By email: cadrmp@hc-sc.gc.ca

By regular mail:
National AR Centre
Marketed Health Products Safety and Effectiveness Information Division
Marketed Health Products Directorate
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals may be obtained by contacting the sponsor, Pfizer Canada Inc., at:
1-800-463-6001

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