



Alternative packaging and more convenient storage options



What to know about flexible packaging options

Original One-Day Package

- One box contains 1 single-dose SOMAVERT vial, 1 prefilled syringe containing 1 mL of diluent (Sterile Water for Injection, USP), and 1 separate 27-gauge 1/2-inch safety needle
- A 30-day supply of one-day packages takes up approximately the **same amount of refrigerator space as 3 gallons of milk**

30-Day Package

- One large carton contains 3 intermediate cartons containing a total of 30 single-dose vials of SOMAVERT, 30 prefilled syringes containing 1 mL of diluent (Sterile Water for Injection, USP), and 30 separate 27-gauge 1/2-inch safety needles
- A 30-day supply of 3 small cartons takes up **less refrigerator space than 2 gallons of milk**

INDICATION

SOMAVERT is a prescription medicine for acromegaly. It is for patients whose disease has not been controlled by surgery or radiation, or patients for whom these options are not appropriate. The goal of treatment with SOMAVERT is to have a normal IGF-I level in the blood.

SELECTED SAFETY INFORMATION

Do not use SOMAVERT® (pegvisomant for injection) if you are allergic to SOMAVERT or anything that is in it.

Be sure to tell your doctor if you use narcotic painkillers (opioid medicines) because the dose of SOMAVERT may need to be changed.

Blood sugar levels may go down when taking SOMAVERT. Be sure to tell your doctor if you use insulin or other medicines (oral hypoglycemic medicines) for diabetes. The dose of these medicines may need to be reduced when you use SOMAVERT.

Some people who have used SOMAVERT have developed liver problems. These problems generally

disappeared when those people stopped taking SOMAVERT.

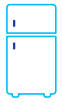
Stop the drug right away and call your doctor if you get any of these symptoms:

- 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 the IGF-I levels in your blood are normal and/or that your liver is working correctly. Your dose of SOMAVERT may be changed based on the results of these tests.

Please see additional Selected Safety Information on reverse and full Prescribing Information in pocket.

What to know about convenient storage options



Refrigerator storage

- Recommended for longer-term storage prior to reconstitution
- **Store SOMAVERT in the refrigerator at 36°F to 46°F (2°C-8°C)** until you need to take it out (for example, to use it or for travel away from home)
- Do **not** freeze SOMAVERT



Discarding SOMAVERT

- Discard the SOMAVERT vial(s) after the expiration date printed on the carton or the discard date, whichever is sooner



SOMAVERT administration

- If you have not used the mixed SOMAVERT immediately, throw it away

Please note: This update applies to all packages of SOMAVERT, although some packages may not contain this updated information on the package insert. Please speak with your pharmacist or healthcare team if you have any questions related to this information.

SOMAVERT itself remains the same. If you need help deciding which package and storage option is best for you, or have any questions about SOMAVERT, please speak with your healthcare provider or pharmacist.

SELECTED SAFETY INFORMATION

If you have stopped SOMAVERT because of an allergic reaction, your doctor will carefully monitor what happens if you start SOMAVERT again.

The most common side effects with SOMAVERT are infection, pain, nausea, diarrhea, abnormal liver function tests, flu-like symptoms, and reaction at the injection site. These are not all of the possible side effects of SOMAVERT. For more information, speak to your doctor.

Inject SOMAVERT in a different place on your body



Convenient room temperature storage*

- Use when refrigerating SOMAVERT is less convenient or not an option
- For convenience, the one-day package and intermediate cartons in the 30-day package containing the SOMAVERT vial(s) **may be stored at room temperature up to 77°F (25°C) for a single period of up to 30 days**
 - In the space provided on the carton, record the date when the carton was removed from the refrigerator and the discard date (30 days after removal from the refrigerator)
 - Once the carton has been stored at room temperature, it should not be placed back into the refrigerator. If not used within 30 days at room temperature, the vial(s) should be discarded
- The prefilled syringe(s) may be stored at a temperature up to 86°F (30°C) until the expiration date printed on the carton, at which point they should be discarded

*Room temperature storage does not apply for the existing stock of SOMAVERT one-day packages. Current supplies of SOMAVERT one-day packages should still be stored in the refrigerator at 36°F to 46°F (2°C-8°C). You should follow the Package Insert instructions for the packaging you have.

each day. This can help prevent skin problems such as lumpiness or soreness.

SOMAVERT has not been studied in pregnant women. It is not known if SOMAVERT passes into the mother's milk or if it can harm the baby.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/MedWatch or call 1-800-FDA-1088.

Please see additional Selected Safety Information on front and accompanying full Prescribing Information in pocket.