

SOMAVERT®

Pegvisomant [rbe]

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SOMAVERT. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using SOMAVERT against the benefits they expect it will have for you.

If you have any concerns about using SOMAVERT, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What SOMAVERT is used for

SOMAVERT is used to treat acromegaly, a disease caused by the body making too much growth hormone, which controls the growth of tissues, organs and bones. This leads to an enlargement of the bones (especially of the hands and feet), and other possible symptoms.

SOMAVERT is a product of biotechnology and contains the active substance pegvisomant. Pegvisomant is similar to human growth hormone, which exists naturally in the human body.

SOMAVERT works by blocking the action of the body's growth hormone.

Ask your doctor if you have any questions about why

SOMAVERT has been prescribed for you.

Your doctor may have prescribed it for another reason.

SOMAVERT is not addictive.

SOMAVERT is available only with a doctor's prescription.

Before you start to use it

When you must not use it

Do not use SOMAVERT if you have an allergy to:

- pegvisomant
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not use SOMAVERT after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using SOMAVERT, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- a tumour in the pituitary gland (a hormonal gland in the brain)
- problems with your blood sugar levels, either too high (diabetes) or too low (hypoglycaemia)
- problems with your blood liver enzyme levels
- liver disease
- obstructive biliary tract disease.

Your doctor may want to carry out some additional tests or take additional precautions before starting treatment.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. SOMAVERT is not recommended during pregnancy.

If you have not told your doctor about any of the above, tell him/her before you start using SOMAVERT.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and SOMAVERT may interfere with each other. These include:

- medicines used to treat diabetes such as insulin or oral hypoglycaemic medicines (which lower your blood sugar levels)
- opioid medicines used to relieve pain.

These medicines may be affected by SOMAVERT or may affect how well it works. You may need different amounts of SOMAVERT,

or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using SOMAVERT.

How to use SOMAVERT

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions in the pack, ask your doctor or pharmacist for help.

How much to use

A starting dose of 80 mg of SOMAVERT will be given to you by your doctor.

Following this, your doctor will tell you how much SOMAVERT you must use each day.

How to use it

SOMAVERT is given by injection under the skin (subcutaneous).

It is important to use a different site every day to prevent the buildup of fatty tissue under the skin at the injection site.

You will be taught how to mix and inject SOMAVERT. It is a good idea to refer to the instruction sheet in the pack each time you mix and inject.

It is very important that you always use SOMAVERT exactly as you have been instructed.

If you are not sure what to do, ask your doctor or pharmacist.

When to use it

Use SOMAVERT at about the same time each day.

Using it at the same time each day will have the best effect. It will also help you remember when to use it.

It does not matter if you use SOMAVERT before or after food.

How long to use it

Continue using SOMAVERT for as long as your doctor tells you.

SOMAVERT helps to control your condition, but does not cure it. It is important to keep using SOMAVERT even if you feel well.

If you forget to use it

Inject the next dose as soon as you remember, and then go back to using SOMAVERT as you would normally.

Do not use a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use SOMAVERT, ask your pharmacist for some hints.

If you use too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131 126) or go to Accident and Emergency (Casualty) at your nearest hospital if you think you or anyone else may have used too much SOMAVERT. Do this even if there are no signs of discomfort or poisoning.

No serious reactions have been reported after an overdose of SOMAVERT.

While you are using SOMAVERT

Things you must do

Keep all your doctor's appointments so that your progress can be checked.

Your doctor will check your liver function and other blood substance levels periodically to prevent

unwanted side effects from happening, and to adjust your dose of SOMAVERT.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using SOMAVERT.

Tell any other doctors, dentists, and pharmacists who treat you that you are using SOMAVERT.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using SOMAVERT.

It may affect other medicines used during surgery.

If you become pregnant while using SOMAVERT, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are using SOMAVERT.

It may interfere with the results of some tests.

Things you must not do

Do not use SOMAVERT to treat any other complaints unless your doctor tells you to.

Do not give SOMAVERT to anyone else, even if they have the same condition as you.

Do not stop using SOMAVERT or lower the dosage without checking with your doctor.

If you stop using it suddenly, your condition may worsen or you may have unwanted side effects.

Things to be careful of

Be careful driving or operating machinery until you know how SOMAVERT affects you.

SOMAVERT may cause dizziness in some people. If you feel dizzy, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel

well while you are using SOMAVERT.

SOMAVERT helps most people with acromegaly, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following:

- soreness, swelling or redness at the injection site
- build-up of fatty tissue under the skin at the injection site
- flu like symptoms
- pain
- nausea
- diarrhoea.

The above list includes the more common side effects of SOMAVERT. They are usually mild and short-lived.

SOMAVERT can also cause changes in the levels of certain substances in your blood. These can only be found when your doctor does tests from time to time to check your progress.

Mild and serious allergic reactions have been reported in some patients using SOMAVERT.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following

- swelling of the face, tongue, lips or throat
- wheezing or trouble breathing
- generalised skin rash or itching
- dizziness.

These are symptoms of a serious allergic reaction and you may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using SOMAVERT

Storage

Keep the vials and diluent syringes in their packs until it is time to use them.

If you take them out of their packs they may not keep well.

Keep the SOMAVERT vials in your refrigerator where the temperature stays between 2° and 8° Celsius. Do not freeze.

The SOMAVERT vials may be stored at room temperature (below 25°C) for a single period of up to 30 days. The vials may not be returned to refrigerated storage after storage at room temperature. They must be discarded if not used within the 30 days of storage at room temperature or the expiry date, whichever is earlier.

Store the diluent syringes at room temperature (below 25°C) or in the refrigerator at 2°C to 8°C. Do not freeze.

Inject your dose of SOMAVERT immediately or within 6 hours after preparation.

If storage is necessary, store in therefrigerator at 2°C to 8°C.

Do not store SOMAVERT or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using SOMAVERT or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like

SOMAVERT comes as a white powder that is mixed with a diluent to form a clear solution for injection.

SOMAVERT powder is contained in a glass vial and the diluent (Water for Injections) is contained in a glass syringe.

SOMAVERT comes in three strengths: 10 mg, 15 mg and 20 mg.

The 10 mg and 15 mg strengths are available in packs of 30's. The 20 mg strength is available in packs of 1's and 30's.

Ingredients

Active Ingredients

SOMAVERT vials contain 10 mg, 15 mg or 20 mg of the active ingredient pegvisomant.

Inactive Ingredients

Each vial of SOMAVERT contains the following inactive ingredients:

- glycine
- mannitol
- dibasic sodium phosphate
- monobasic sodium phosphate monohydrate

The diluent syringes contain sterile Water for Injections.

Supplier

SOMAVERT is supplied in Australia by:

Pfizer Australia Pty Ltd
Sydney NSW

Toll Free Number: 1800 675 229

*Australian Registration
Numbers*

SOMAVERT 10 mg AUST R
286628

SOMAVERT 15 mg AUST R
286629

SOMAVERT 20 mg AUST R
286630

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