

SOMAVERT®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using SOMAVERT?

SOMAVERT contains the active ingredient pegvisomant. 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.

For more information, see Section [1. Why am I using SOMAVERT?](#) in the full CMI.

2. What should I know before I use SOMAVERT?

Do not use SOMAVERT if you have ever had an allergic reaction to pegvisomant or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use SOMAVERT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines and SOMAVERT may interfere with each other.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use SOMAVERT?

- A starting dose of 80 mg will be given to you by your doctor. Following this your doctor will tell you how much SOMAVERT you must use each day.
- You will be taught how to mix and inject SOMAVERT.

More instructions can be found in Section [4. How do I use SOMAVERT?](#) in the full CMI.

5. What should I know while using SOMAVERT?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using SOMAVERT.• Continue using SOMAVERT for as long as your doctor tells you to.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or lower the dose without checking with your doctor.• Do not shake the mixed vial. Shaking may damage the medicine.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how SOMAVERT affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep the SOMAVERT vials and the diluent syringes in their packs until it is time to use them.• Store the SOMAVERT vials in the refrigerator at 2-8°C. Do not freeze.• Store the diluent syringes at room temperature (below 25°C) or in the refrigerator at 2-8°C. Do not freeze.

For more information, see Section [5. What should I know while using SOMAVERT?](#) in the full CMI.

6. Are there any side effects?

Common side effects are soreness, swelling or redness at the site of injection, a build-up of fatty tissue under the skin at the injection site, flu-like symptoms, pain, nausea and diarrhoea. Serious side effects 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, dizziness. These are symptoms of an allergic reaction.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

SOMAVERT®

Active ingredient(s): *pegvisomant (rbe)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SOMAVERT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SOMAVERT.**

Where to find information in this leaflet:

- [1. Why am I using SOMAVERT?](#)
- [2. What should I know before I use SOMAVERT?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use SOMAVERT?](#)
- [5. What should I know while using SOMAVERT?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using SOMAVERT?

SOMAVERT contains the active ingredient pegvisomant. Pegvisomant is a product of biotechnology and is similar to human growth hormone, which exists naturally in the human body. Pegvisomant works by blocking the action of the body's growth hormone.

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.

2. What should I know before I use SOMAVERT?

Warnings

Do not use SOMAVERT if:

- you are allergic to pegvisomant or any of the ingredients listed at the end of this CMI.
- Always check the ingredients to make sure you can use this medicine.

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.
- take any medicines for any other condition.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

SOMAVERT is not recommended during pregnancy.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SOMAVERT.

4. How do I use SOMAVERT?

How much to use

- A starting dose of 80 mg will be given to you by your doctor.
- Following this, your doctor will tell you how much SOMAVERT to use each day.
- Follow the instructions provided and use SOMAVERT until your doctor tells you to stop.

When to use SOMAVERT

- SOMAVERT should be used 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 to use SOMAVERT

- SOMAVERT is given by injection under the skin (subcutaneous).
- It is important to use a different injection 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.

- Inject your dose of SOMAVERT immediately or within 6 hours after preparation. If storage is necessary, store in the refrigerator at 2-8°C.
- It is important that you always use SOMAVERT exactly as you have been instructed.

When you mix SOMAVERT, gently swirl the vial to dissolve the powder. Do not shake the vial as this may damage the medicine. After mixing check to make sure that the powder is completely dissolved and the solution is clear. Do not inject if the solution is cloudy or has particles in it.

It is a good idea to refer to the Instructions for Use provided in the pack on the correct way to prepare and inject SOMAVERT each time you use it.

How long to use SOMAVERT

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

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

If you forget to use SOMAVERT

SOMAVERT should be used at about the same time each day. If you miss your dose at the usual time, 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 you missed.

This may increase the chance of you getting unwanted side effects.

If you use too much SOMAVERT

If you think that you have used too much SOMAVERT, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using SOMAVERT?

Things you should 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, 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.

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 are about to have any blood tests, tell your doctor that you are using SOMAVERT. It may interfere with the results of some tests.

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

Remind any doctor, dentist or pharmacist you visit that you are using SOMAVERT.

Things you should not do

- Do not stop using this medicine suddenly or lower the dose without checking with your doctor. If you stop using SOMAVERT suddenly your condition may worsen or you may have unwanted side effects.
- Do not heat or freeze your mixed or unmixed SOMAVERT.
- Do not give your SOMAVERT to anyone else.
- Do not shake the mixed SOMAVERT vial as shaking may damage the medicine.

Driving or using machines

Be careful before you drive or use any machines or tools 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 may be dangerous.

Looking after your medicine

- Keep the SOMAVERT vials and the diluent syringes in their cartons in order to protect from light.
- Keep the SOMAVERT vials in the refrigerator at 2-8°C. Do not freeze.
- The carton(s) containing 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 2-8°C. Do not freeze.

Follow the instructions in the carton on how to take care of your medicine properly.

Do not store or leave SOMAVERT:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep SOMAVERT where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
Administration site disorders: <ul style="list-style-type: none">• soreness, swelling or redness at the injection site• build-up of fatty tissue under the skin at the injection site. Gastrointestinal disorders: <ul style="list-style-type: none">• diarrhoea• nausea General disorders: <ul style="list-style-type: none">• flu-like symptoms• pain	Speak to your doctor if you have any of these side effects and they worry you.

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.

Serious side effects

Serious side effects	What to do
Allergic reactions: <ul style="list-style-type: none">• swelling of the face, tongue, lips, throat or other parts of the body• wheezing or trouble breathing• generalised skin rash, hives (urticaria) or itching• dizziness.	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What SOMAVERT contains

Active ingredient (main ingredient)	pegvisomant
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Other ingredients (inactive ingredients)	glycine, mannitol, dibasic sodium phosphate, monobasic sodium phosphate monohydrate, water for injections
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Do not use this medicine if you are allergic to any of these ingredients.

What SOMAVERT 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. The 20 mg strength is available in packs of 1 and 30.

SOMAVERT 10 mg: AUST R 286628

SOMAVERT 15 mg: AUST R 286629

SOMAVERT 20 mg: AUST R 286630

Who distributes SOMAVERT

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229 www.pfizermedinfo.com.au

This leaflet was prepared in January 2023.