SIDE A

Package leaflet: Information for the user

SOMAVERT®
10, 15, 20, 25, 30 mg powder and solvent for solution for injection

pegvisomant

PAA212080
433

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What SOMAVERT is and what it is used for

SOMAVERT is used for the treatment of acromegaly, a hormonal disorder resulting from the increased secretion of growth hormone (GH) and IGF-I (insulin-like growth factors), which is characterised by overgrowth of bone, soft tissue swelling, heart disease and related disorders.

The active substance in SOMAVERT, pegvisomant is known as a growth hormone receptor antagonist. These substances decrease the action of GH and levels of IGF-I circulating in the blood.

2. What you need to know before you use SOMAVERT

Do not use SOMAVERT
- If you are allergic to pegvisomant or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using SOMAVERT.
- If you experience disturbed vision or headaches you must contact your doctor immediately.
- Your doctor or nurse will monitor the levels of IGF-I (insulin-like growth factors) circulating in the blood and adjust the dose of SOMAVERT if necessary.
- Your doctor should also monitor your adenoma (benign tumour).
- Your doctor will conduct tests of your liver function before starting and during treatment with SOMAVERT. If these test results are not normal, your doctor will discuss treatment options with you. Once treatment begins, your doctor or nurse will monitor the level of liver enzymes in the blood every 4-6 weeks for the first 6 months of treatment with SOMAVERT. Administration of SOMAVERT should be discontinued if signs of liver disease persist.
- If you are diabetic, your doctor may need to adjust the amount of insulin or other medicines you are using.
- Fertility in women patients may be increased as the disease improves. The use of this medicine in pregnant women is not recommended and women of childbearing age should be advised to use a contraception. See also the section about Pregnancy below.

Other medicines and SOMAVERT

You must tell your doctor if you have previously used other medicines for the treatment of acromegaly or medicines for the treatment of diabetes.

Tell your doctor or pharmacist if you are using or have recently used any other medicines.

As part of your treatment you may be given other medicines. It is important to keep using all your medicines as well as SOMAVERT unless you are told otherwise by your doctor, pharmacist or nurse.

Pregnancy, breast-feeding and fertility

The use of SOMAVERT in pregnant women is not recommended. If you are a woman of childbearing age, a contraception should be used during treatment.

It is not known if pegvisomant passes into breast milk. You should not breast-feed while taking SOMAVERT unless your doctor has discussed this with you.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

SOMAVERT contains sodium

This medicine contains less than 1 mmol of sodium (23 mg) per dose i.e. essentially 'sodium-free'.

3. How to use SOMAVERT

Always inject this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

A starting dose of 80 mg of pegvisomant will be given subcutaneously (just under the skin) by your doctor. Following this, the usual daily dose of pegvisomant is 10 mg, which is given by subcutaneous injection (just under the skin).

Every four to six weeks your doctor will make appropriate dose adjustments, made in increments of 5 mg pegvisomant/day, based on your so-called serum IGF-I levels to maintain an optimal therapeutic response.

Method and route of administration

SOMAVERT is injected under the skin. The injection can be self-administered or given by another person, for example your doctor or his/her assistant. The detailed instructions on injection procedure provided at the end of this leaflet must be followed. You should continue to inject this medicine for as long as instructed by your doctor.

This medicine must be dissolved before use. The injection must not be mixed in the same syringe or vial as any other medicine.

Fatty tissue of the skin can build-up at the site of injection. To avoid this, use a slightly different place for your injection each time, as described in Step 2 of the 'instructions for preparing and giving an injection of SOMAVERT' section of this leaflet. This gives your skin and the area under your skin time to recover from one injection before it receives another one in the same place.

If you have the impression that the effect of this medicine is too strong or too weak, talk to your doctor, pharmacist or nurse.

If you inject more SOMAVERT than you should

If you accidentally inject more SOMAVERT than told to by your doctor it is unlikely to be serious, but you should contact your doctor, pharmacist or nurse immediately.

If you forget to use SOMAVERT

If you forget to give yourself an injection you should inject the next dose as soon as you remember and then continue to inject SOMAVERT as prescribed by your doctor. Do not inject a double dose to make up for forgotten individual doses.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Mild to serious allergic (anaphylactic) reactions have been reported in some patients taking SOMAVERT. Symptoms of a serious allergic reaction may include one or more of the following: swelling of the face, tongue, lips, or throat; wheezing or trouble breathing (spasm of the larynx); generalized skin rash, nettle rash (urticaria) or itching; or dizziness. Contact your doctor immediately if you develop any of these symptoms.

Very common: may affect more than 1 in 10 people
- Headache
- Diarrhoea
- Joint pain

Common: may affect up to 1 in 10 people
- Shortness of breath.
- Increased levels of substances that measure the function of the liver. These can be seen in the results of blood tests.
- Blood in the urine.
- Increased blood pressure.
- Constipation, feeling sick, being sick, feeling bloated, indigestion, gas.
- Dizziness, sleepiness, uncontrolled trembling, decreased sense of touch.
- Bruising or bleeding at injection site, soreness or swelling at injection site, build up of fat below the surface of the skin at injection site, swelling of the extremities, weakness, fever.
- Sweating, itching, rash, tendency to bruise.
- Muscle pain, arthritis.
- Increased blood cholesterol, weight gain, increased blood glucose, decreased blood glucose.
- Flu-like illness, fatigue.
- Abnormal dreams.
- Eye pain.

Uncommon: may affect up to 1 in 100 people
- Allergic reaction after administration (fever, rash, pruritus and, in severe cases, difficulty to breathe, rapid swelling of skin, requiring urgent medical attention). May occur immediately, or several days after administration.
- Protein in the urine, increased urine, kidney problems.
- Lack of interest, feeling confused, increased sex drive, panic attack, loss of memory, problems sleeping.
- Decreased platelets in the blood, increased or decreased white cells in the blood, tendency to bleed.
- Feeling abnormal, impaired healing.
- Eyestrain, inner ear problems.
- Facial swelling, dry skin, night sweats, redness of the skin (erythema), raised itchy bumps on the skin (urticaria).
- Increased fatty substances in the blood, increased appetite.
- Dry mouth, increased saliva, tooth problems, haemorrhoids.
- Abnormal sense of taste, migraine.

Not known: frequency cannot be estimated from the available data
- Anger
- Severe breathlessness (laryngospasm)
- Rapid swelling of skin and underlying tissue and inner lining (mucosa) of organs (angioedema)

About 17% of patients will develop antibodies to growth hormone during treatment. The antibodies do not seem to stop this medicine from working.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store SOMAVERT

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial and the carton after EXP. The expiry date refers to the last day of that month.

Store the powder vial(s) in a refrigerator (2°C – 8°C) in their carton(s) in order to protect from light.
Do not freeze.
The carton(s) containing the SOMAVERT powder vial(s) may be stored at room temperature up to a maximum of 25°C for a single period of up to 30 days. Write the Use by date on the carton including day/month/year (up to 30 days from the date removed from the refrigerator). The vial(s) must be protected from light. Do not return this medicine to refrigerator.

Discard this medicine if not used by the new Use by date or the expiry date printed on the carton, whichever is earlier. Store the pre-filled syringe(s) below 30°C or store in a refrigerator (2°C – 8°C). Do not freeze.

After preparing the SOMAVERT solution it must be used immediately.

Do not use this medicine if you notice that the solution is cloudy or contains particulate matter.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What SOMAVERT contains
- The active substance is pegvisomant.
- SOMAVERT 10 mg: One vial of powder contains 10 mg pegvisomant. After reconstitution with 1 ml of solvent, 1 ml of the solution contains 10 mg pegvisomant.
- SOMAVERT 15 mg: One vial of powder contains 15 mg pegvisomant. After reconstitution with 1 ml of solvent, 1 ml of the solution contains 15 mg pegvisomant.
- SOMAVERT 20 mg: One vial of powder contains 20 mg pegvisomant. After reconstitution with 1 ml of solvent, 1 ml of the solution contains 20 mg pegvisomant.
- SOMAVERT 25 mg: One vial of powder contains 25 mg pegvisomant. After reconstitution with 1 ml of solvent, 1 ml of the solution contains 25 mg pegvisomant.
- SOMAVERT 30 mg: One vial of powder contains 30 mg pegvisomant. After reconstitution with 1 ml of solvent, 1 ml of the solution contains 30 mg pegvisomant.
- The other ingredients are glycine, mannitol (E421), disodium phosphate anhydrous and sodium dihydrogen phosphate monohydrate (see section 2 "SOMAVERT contains sodium").
- The solvent is water for injections.

What SOMAVERT looks like and contents of the pack

SOMAVERT is presented as a powder and a solvent for injection (either 10 mg, 15 mg, 20 mg, 25 mg or 30 mg pegvisomant in a vial and 1 ml of solvent in a pre-filled syringe). Pack sizes of 1 and/or 30. Not all pack sizes are marketed. The powder is white and the solvent is clear and colourless.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder:

Pfizer Limited
Ramsgate Road
Sandwich
Kent
CT13 9NJ
United Kingdom

Manufacturer:

Pfizer Manufacturing Belgium NV
Rijksweg 12
2870 Puurs-Sint-Amands
Belgium

For any information about this medicine, please contact:
Medical Information, Pfizer Ltd, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS. Telephone 01304 616161.

This leaflet was last revised in 11/2023

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Ref: SV 21_0

SIDE B

See over for **INSTRUCTIONS FOR USE**

RECTO

Process Black

Pfizer PUURS		Perigord	Date: 29 Jul 2023	Time: 15:50		Print Colors	Non-Print Colors
Component Code	PAA212080	Version/Proof	01	Barcode No.	N/A	Black	
Component Type	N/A	Site/CMO	Puurs	Smallest Body Text Size	8.14 pt	PC Process Blue	
Market	Great Britain	Layout	1139/E_08	PAR Number	PAR-2023-0005456		
Size	930 x 310 mm			ITF / DM	Data matrix - PAA212080		
Description	N/A			Source Code	433		

VERSO

INSTRUCTIONS FOR USE

SOMAVERT powder in vial with solvent in a pre-filled syringe

pegvisomant for injection
For Subcutaneous Injection Only
single dose vial

SOMAVERT comes in a vial as a white block of powder. You must mix SOMAVERT with a liquid (diluent) before you can use it.
The liquid comes in a pre-filled syringe labeled 'Solvent for SOMAVERT'.
Do not use any other liquid to mix with SOMAVERT.

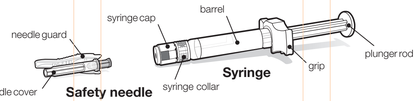
It is important that you do not try to give yourself or someone else an injection unless you have received training from your healthcare provider.

Store the carton(s) of powder vials in the refrigerator at 2°C to 8°C and away from direct sunlight.
The carton(s) containing the SOMAVERT powder vial(s) may be stored at room temperature up to a maximum of 25°C for a single period of up to 30 days. Write the Use by date on the carton including day/month/year (up to 30 days from the date removed from the refrigerator). The vial(s) must be protected from light. Do not return this medicine to refrigerator.
Discard this medicine if not used by the new Use by date or the expiry date printed on the carton, whichever is earlier.
The pre-filled solvent syringe may be stored at room temperature. Keep out of reach of children.

1 Things you need

A single SOMAVERT pack containing:
- A vial of SOMAVERT powder.
- A pre-filled syringe with solvent.
- A safety needle.

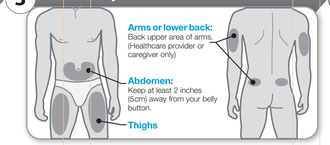
You will also need:
- A cotton ball.
- An alcohol swab.
- A suitable sharps container.



2 Getting ready

Before you start:
- Only mix SOMAVERT and the solvent when you are ready to inject your dose.
- Remove a single SOMAVERT pack from the refrigerator and allow it to come to room temperature naturally in a safe place.
- Wash your hands with soap and water, and dry thoroughly.
- Peel open the packaging of the syringe and safety needle to make it easier to pick up each item as you prepare for your injection.
- Do not use the syringe or vial if:
  - o they are damaged or faulty;
  - o the expiration date has passed;
  - o it has been frozen, even if it has now thawed (syringe only).

3 Choose injection area

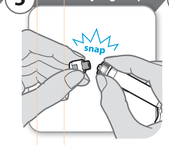


3. Choose injection area
- Choose a different location within an area for each injection.
- Avoid bony areas or areas that are bruised, red, sore or hard, or areas that have scars or skin conditions.
- Clean the injection area with the alcohol swab as instructed by your healthcare provider.
- Allow the injection area to dry.

4 Remove vial cap

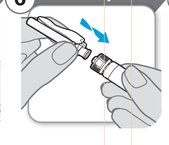
4. Remove vial cap
- Remove the cap from the vial.
- Throw the cap away; it is not needed again.
  Caution: Do not let anything touch the vial stopper.

5 Remove syringe cap



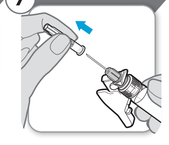
5. Remove syringe cap
- Snap off the syringe cap. It may take more effort to snap off than you might expect.
- Throw the syringe cap away; it is not needed again.
- Keep the syringe upright to avoid leakage.
  Caution: Do not let the end of the syringe touch anything when the syringe cap is off.

6 Attach safety needle



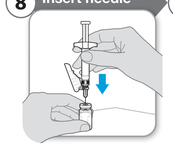
6. Attach safety needle
- Twist the safety needle firmly onto the syringe as far as it will go.

7 Remove needle cover



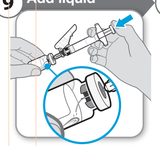
7. Remove needle cover
- Fold the needle guard out of the way of the needle cover.
- Carefully pull the needle cover straight off.
- Throw the needle cover away; it is not needed again.
  Caution: Do not let the needle touch anything.

8 Insert needle



8. Insert needle
- Push the needle through the centre of vial stopper, as shown.
- Support the syringe while the needle is in the vial stopper to prevent bending the needle.

9 Add liquid



9. Add liquid
- Tilt both the vial and syringe at an angle, as shown.
- Push the plunger rod down **slowly** until all the liquid has emptied into the vial.
- **Caution:** Do not squirt the liquid directly onto the powder, as this creates foam. Foam makes the medicine unusable.
- **Do not withdraw the needle yet.**

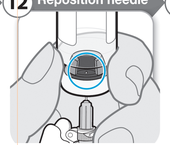
10 Swirl vial

10. Swirl vial
- Support both the syringe and vial in one hand, as shown.
- Gently swirl the liquid, sliding the vial in a circular motion on a flat surface.
- Continue swirling the liquid until all the powder has fully dissolved.
  Note: This may take up to 5 minutes.

11 Check medicine

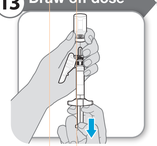
11. Check medicine
- Keeping the needle in the vial, look carefully at the medicine. It must be clear and free of particles.
- Do not use if:
  - o the medicine is cloudy or hazy;
  - o the medicine has any colour at all;
  - o there are any particles or there is a layer of foam in the vial.

12 Reposition needle



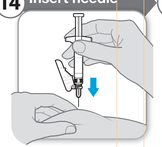
12. Reposition needle
- Turn the vial so that you can see the stopper gap, as shown.
- Pull the needle down so that the needle tip is at the lowest point in the liquid. This will help you to draw off as much liquid as possible.
- Check that the plunger rod has not moved—if it has, then push it back all the way into the syringe. This ensures that all air is removed from the syringe before you draw off the dose.

13 Draw off dose



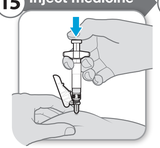
13. Draw off dose
- Slowly pull back the plunger rod to withdraw as much medicine as possible from the vial.
  Note: If you see air in the syringe, tap the barrel to float the bubbles to the top,and then gently push the bubbles out **into the vial**.
- Pull the needle out of the vial.

14 Insert needle



14. Insert needle
- Gently pinch the skin at the site of injection.
- Insert the needle to its full depth into the pinched skin.

15 Inject medicine

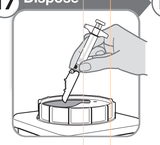


15. Inject medicine
- Push the plunger rod down slowly until the barrel is empty.
  Note: Make sure you keep the needle in at full depth.
- Release the pinched skin and pull the needle straight out.

16 Make needle safe

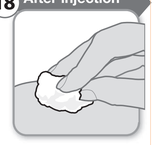
16. Make needle safe
- Fold the needle guard over the needle.
- **Gently** apply pressure using a hard surface to lock the needle guard in place.
  Note: You will hear a click when the needle guard has been locked.

17 Dispose



17. Dispose
- The syringe and needle should **NEVER** be reused. Dispose of the needle and syringe as instructed by your doctor, nurse or pharmacist and in accordance with local health and safety laws.

18 After injection



18. After injection
- If necessary, use a clean cotton ball and press lightly on the injection area.
- **Do not rub the area.**

QUESTIONS & ANSWERS

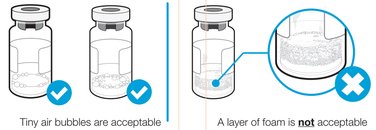
What should I do if anything has accidentally touched the vial stopper?
- Clean the vial stopper with a fresh alcohol wipe, and leave it to dry completely. If you are unable to clean the stopper, do not use the vial.

What should I do with the syringe if it has been dropped?
- Do not use it—even if it looks undamaged. Dispose of the syringe in the same way as a used syringe. You will need a replacement syringe.

How many times can I safely insert the needle into the vial stopper?
- Once only. Withdrawing and reinserting greatly increases the risk of needle damage, and will blunt the needle. This can cause discomfort and increases risk of skin damage and infection. There is also a risk you may lose some of the medicine.

Is it OK to shake the vial if the powder is not dissolving?
- No—never shake the vial. Shaking can destroy the medicine and create foam. The powder may take a few minutes to dissolve fully, so continue swirling the vial gently until the liquid is completely clear.

How can I tell if there is any foam in the vial?
- Foam looks like a mass of small bubbles that float as a layer to the top of the liquid. Do not inject SOMAVERT if it has foamed.



Tiny air bubbles are acceptable

A layer of foam is **not** acceptable

How can I prevent the medicine from foaming?
- Press the plunger very slowly so that the liquid gently runs down the inside of the vial. Do not spray the liquid directly onto the powder, as this creates foam. This technique will also reduce the swirling time and allow more of the medicine to be drawn off.

I can see some air in the syringe. Is this OK?
- Tiny air bubbles in the liquid are normal and are safe to inject. However, it is possible to accidently draw air into the syringe, which should be removed before injecting. Bubbles or air gaps that float to the top of the liquid should be pushed back out into the vial.

Why can't I get all of the medicine out of the vial?
- The shape of the vial means that a very small amount of the medicine will be left behind in the vial. This is normal. To ensure that only a trace of medicine remains, make sure the needle tip is as low as it can be in the vial when drawing off your dose.

What should I do if I have any doubts about my medicine?
- All questions should be handled by a doctor, nurse or pharmacist familiar with SOMAVERT.

INSTRUCTIONS FOR USE SIDE **B**

PAA212080

NO FOLD AREA

Process Black PMS Process Blue

Pfizer PUURS		Peregrid Perigord	Date: 29 Jul 2023	Time: 15:50	Print Colors	Non-Print Colors
Component Code	PAA212080	Version/Proof	01	Barcode No. N/A	Black	
Component Type	N/A	Site/CMO	Puurs	Smallest Body Text Size 8.14 pt	PMS Process Blue	
Market	Great Britain	Layout	1139/E_08	PAR Number PAR-2023-0005456		
Size	930 x 310 mm			ITF / DM Data matrix - PAA212080		
Description	N/A			Source Code 433		