

**SOMAVERT**[®]
(pegvisomant for injection)

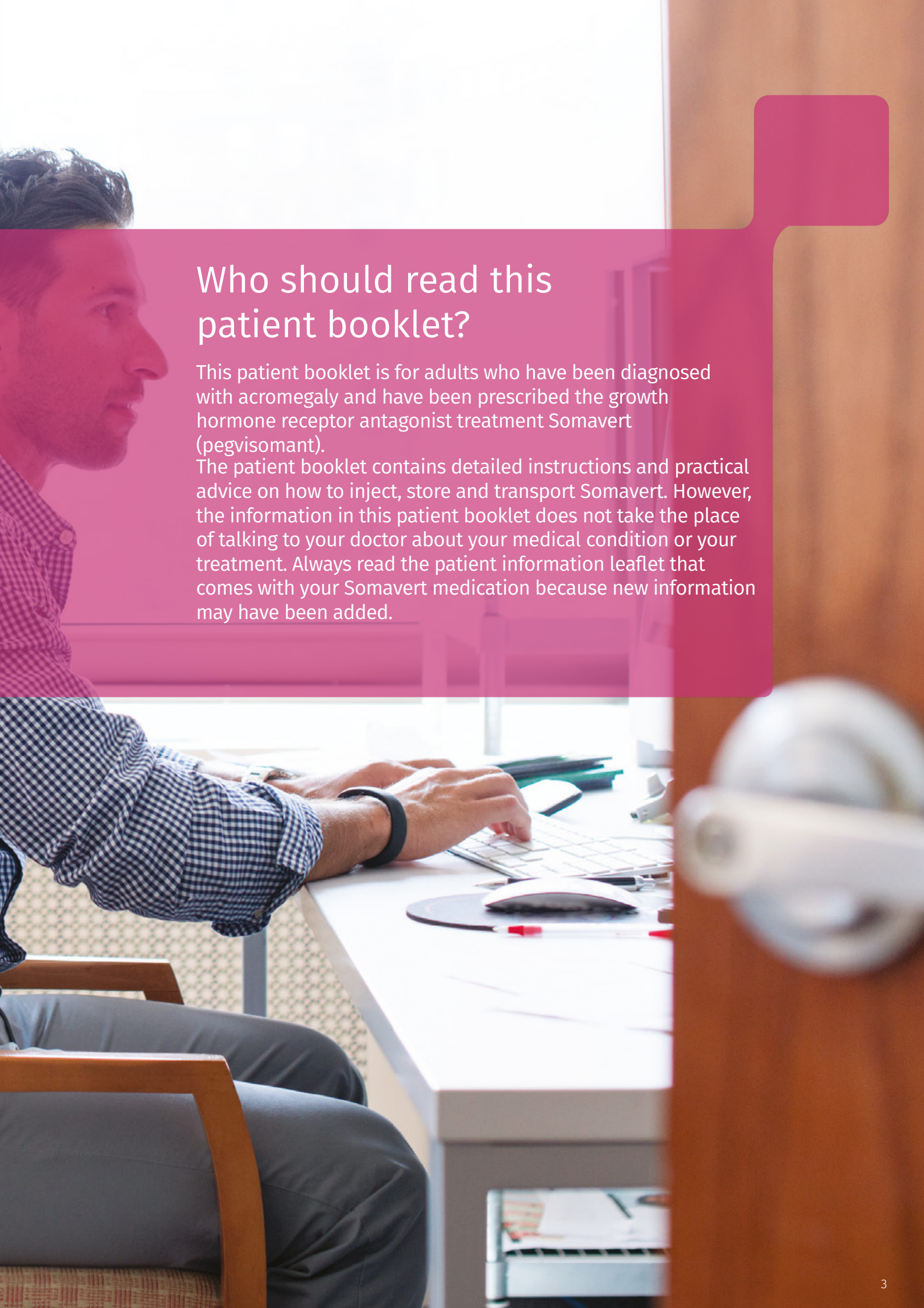
What you need to know about Somavert[®] (pegvisomant)

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 the package leaflet. You can also report side effects directly via the Yellow Card Scheme at: <https://yellowcard.mhra.gov.uk/> 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.

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Who should read this patient booklet?

This patient booklet is for adults who have been diagnosed with acromegaly and have been prescribed the growth hormone receptor antagonist treatment Somavert (pegvisomant).

The patient booklet contains detailed instructions and practical advice on how to inject, store and transport Somavert. However, the information in this patient booklet does not take the place of talking to your doctor about your medical condition or your treatment. Always read the patient information leaflet that comes with your Somavert medication because new information may have been added.

Somavert Instructions for use¹

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

- 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 labelled '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 powder vials in the refrigerator at 2°C – 8°C. Do not freeze. Keep 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. The Use by date should be written on the carton (up to 30 days from the date removed from the refrigerator). The vial(s) must be protected from light and should not be placed back into the refrigerator. The SOMAVERT powder vial(s) must be discarded if not used within the 30 days of room temperature storage or the expiry date printed on the carton, whichever is earlier.
- Store the pre filled syringe below 30°C or store in refrigerator at 2°C – 8°C. Do not freeze
- Keep out of reach of children

Step 1: Things you need

A single vial of 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



Step 2: Getting ready

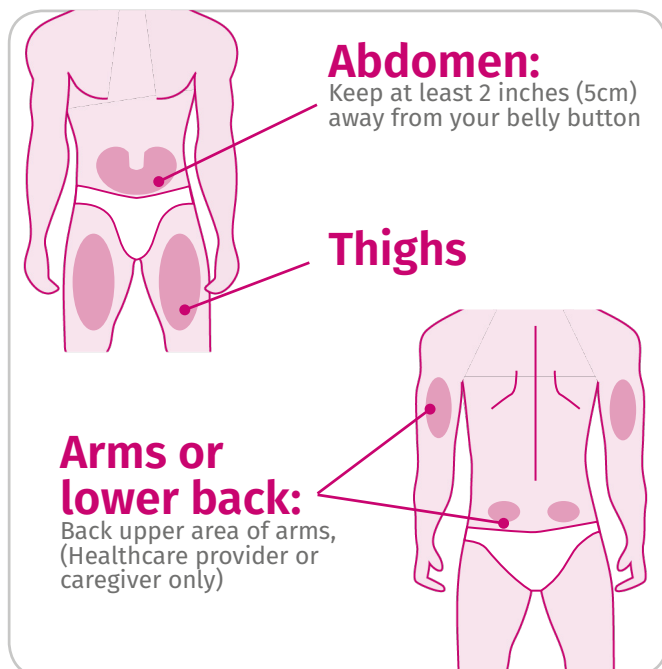
Before you start

- 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:
 - they are damaged or faulty;
 - the expiration date has passed;
 - it has been frozen, even if it has now thawed (syringe only)



Step 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



Step 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



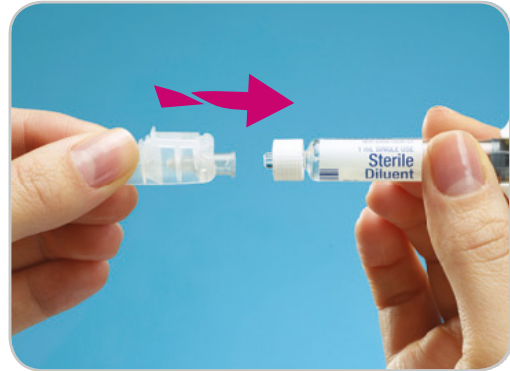
Step 5: Remove syringe cap

- 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



Step 6: Attach safety needle

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



Step 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



Step 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



Step 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**



Step 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



Step 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:
 - the medicine is cloudy or hazy;
 - the medicine has any colour at all;
 - there are any particles or if there is a layer of foam in the vial



Step 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



Step 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



Step 14: Insert needle

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



Step 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



Step 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



Step 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



Step 18: After injection

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



Frequently asked questions about Somavert

Why have I been prescribed Somavert?

Your healthcare professional has prescribed you Somavert for your acromegaly. Somavert must not be taken if you are allergic to its active ingredient (pegvisomant) or any of the other components.

How does Somavert work?

The active ingredient, pegvisomant, is a growth hormone receptor antagonist that reduces the action of growth hormone and levels of insulin-like growth factor 1 (IGF-1) circulating in the blood. Restoring IGF-1 to normal levels reduces the symptoms of acromegaly.

How will my doctor know if my levels of IGF-1 are falling?

Your doctor will regularly measure the levels of IGF-1 in your blood. Based on the results, your doctor will calculate the correct dose of Somavert for you. This will help to maintain the amount of IGF-1 in your body at the correct levels for your age.

How quickly will Somavert improve my symptoms?

Clinical studies have examined how well Somavert works. One study treated groups of acromegaly patients with different doses of Somavert, while another group was treated with an inactive substance (placebo) for 12 weeks. Neither the patients nor the doctors knew which treatment was being dosed.²

Most patients treated with Somavert experienced a rapid reduction of IGF-1 occurring within 2 weeks, while the patients treated with the placebo did not. The reduction of IGF-1 is dependent on the dose: more patients achieved normal IGF-1 levels with higher doses of Somavert. However this does not mean the highest dose is the best, your doctor will know how to adjust the dose so that it is right for you.²

Somavert also improved the signs and symptoms of acromegaly after 12 weeks compared with the placebo treatment. Improvements were noted in relation to excessive perspiration, fatigue and swelling of the soft tissues of the body.²

Frequently asked questions about Somavert

How long will I have to take Somavert?

Treatment with Somavert is usually lifelong. Somavert treatment starts with or continues until the pituitary tumour has been removed by a further surgery.

Somavert treatment starts with a daily dose of 10 mg via a subcutaneous (under the skin) injection, following a single loading dose of 80 mg. Your levels of IGF-1 are then measured every 4–6 weeks to check if Somavert is working for you.

Your dose of Somavert will be increased or reduced until your IGF-1 values are within a normal range for your age. This method of dose adjustment is known as titration and aims to restore your IGF-1 to normal levels. Somavert can be increased to a maximum dose of 30 mg/day if necessary.³

What side effects does Somavert have?

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most of the side effects of Somavert in clinical studies were mild to moderate, lasted only briefly and did not require patients to stop treatment.

The most commonly reported side effects occurring in $\geq 10\%$ of patients with acromegaly treated with Somavert during clinical trials were headache 25%, joint pain 16% and diarrhoea 13%.³

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. Please refer to the patient information leaflet for further information on side effects.

The site of the injection should be rotated daily to help prevent a build up of fat below the surface of the skin at the injection site.

Your liver function must be checked at intervals of 4–6 weeks during the first 6 months of treatment with Somavert or immediately if you show any symptoms that suggest inflammation of the liver. Somavert treatment must be stopped if signs of liver disease continue.³

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 the package leaflet. You can also report side effects directly via the Yellow Card Scheme at:

<https://yellowcard.mhra.gov.uk/> 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.

How do I use Somavert?

Somavert is injected once daily under the skin (arms or lower back, abdomen, thighs). Normally, a specialist nurse will give you your first injection. The nurse will show you how to prepare the solution and how to inject it, after which you will be able to inject Somavert yourself.

What is the best time to inject Somavert?

You can inject Somavert at a time convenient to you, but this should be done at the same time every day. For example, if you inject yourself in the morning, then you should do so every day. For daily injections, it is important you choose a time of day that suits your own personal routine.

What do I do if I have problems injecting Somavert?

If you experience problems after you inject, such as pain and bruising, you may be using an incorrect technique. Tips to make your Somavert injection more comfortable:

- Make sure the area of skin you are going to use is clean and dry before injecting
- Gently pinch a fold of skin between your thumb and index finger
- Insert the needle in one fluid movement at right angles to the skin fold
- With the needle positioned in the skin fold, inject until the syringe is empty
- Release the skin fold and then gently withdraw the needle from the skin
- Do not rub or scratch the injection site
- Change the injection site every day

How far in advance can I prepare my Somavert injection?

You must administer the injection of Somavert as soon as you have prepared it. Do not prepare the solution and then wait to inject.

How should I store Somavert?

- Store the powder vials in their carton(s) in the refrigerator at 2°C – 8°C. Do not freeze. Keep 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 earlier¹
- Store the pre filled syringe below 30°C or store in refrigerator at 2°C – 8°C. Do not freeze

What do I do if the prepared solution for injection is cloudy or not clear?

Do NOT use Somavert if the solution is cloudy. When you prepare an injection, the fluid in the vial must be clear when the powder has fully dissolved. If the solution is cloudy or slightly coloured, or if there are particles floating in the solution, then you must return the Somavert vial to your pharmacist and request a replacement.

What do I do if I forget my daily injection?

If you forget to inject Somavert, then you should inject the next dose as soon as you remember and then continue to inject Somavert as prescribed by your doctor. Simply continue with the next injection on the next day, but NEVER inject a double dose if you have forgotten an injection.¹

Frequently asked questions about Somavert

What do I do if I inject more Somavert than I should?

If you inject more Somavert than the amount prescribed you should contact your doctor or pharmacist.

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?

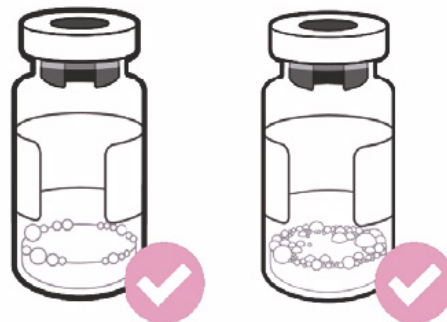
Once only. Withdrawing and reinserting greatly increases the risk of needle damage, and will blunt the needle. This can cause discomfort and increases risk of skin damage and infection. There is also a risk you may lose some of the medicine.

Is it OK to shake the vial if the powder is not dissolving?

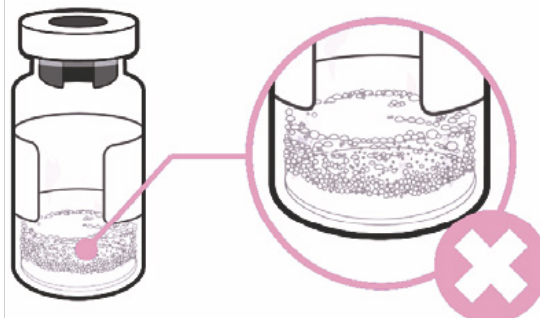
No – never shake the vial. Shaking can destroy the medicine and create foam. The powder may take a few minutes to dissolve fully, so continue swirling the vial gently until the liquid is completely clear.

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 accidentally 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.

Can I use Somavert if I have diabetes?

Yes. Some people may become more sensitive to insulin when they start Somavert treatment. Some people with diabetes can experience low blood sugar (hypoglycaemia). If this happens, your doctor will ask you to check your blood sugar levels and lower your dose of insulin or other diabetes drugs.³

Can I take Somavert during pregnancy?

The effect of Somavert during pregnancy is unknown, so the use of Somavert in pregnant women is not recommended. If you are pregnant, or wish to become pregnant, you should discuss it with your doctor.

Can I take Somavert with me on holiday?

As usual, you must store Somavert in a cold place wherever possible (2–8°C). If you are travelling, you should place Somavert in a cool bag with a cool block. NEVER freeze Somavert and always protect it from light.

If you think you may have a problem storing Somavert properly on holiday or while travelling, discuss your plans with your doctor or nurse beforehand.

References:

1. Somavert patient information leaflet
2. Trainer P, et al. N Engl J Med 2000; 342:1171–1177
3. Somavert Summary of Product Characteristics