

SAIZEN[®]

Somatropin (rmc), recombinant human growth hormone

New Zealand Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SAIZEN.

It does not contain all of the available information.

It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of using SAIZEN against the benefits it is expected to have for you.

If you have any concerns about using this medicine, ask your doctor, nurse or pharmacist.

Keep this information with the medicine.

You may want to read it again later.

What SAIZEN is used for

SAIZEN is used to treat:

- Growth failure in children who have a deficiency of natural human growth hormone.
- Growth failure in girls who have gonadal dysgenesis, often referred to as Turner Syndrome.
- Growth hormone deficiency in adults.

SAIZEN contains somatropin, which is identical to natural human growth hormone, but is made in a laboratory.

Your doctor may have prescribed SAIZEN for another reason. If you are unsure as to why you have been prescribed SAIZEN, ask your doctor.

SAIZEN is available only on a doctor's prescription.

Before you use SAIZEN

When you must not use it

Do not use SAIZEN if you have an allergy to:

- somatropin
- any of the other 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 SAIZEN if:

- You currently have any type of active cancer
All cancer treatments must be finished before starting treatment with SAIZEN.
- You are being treated for an active brain lesion, e.g. brain injury, abscess or tumour
- You have diabetic retinopathy, an eye disease caused by complications of diabetes.
- You have an acute, critical illness, e.g. following major surgery, or hospitalisation for an accident, or severe breathing disorders.

SAIZEN should not be used for growth promotion in children if their bones have stopped growing.

Do not use SAIZEN after the expiry date printed on the pack.

If you use this medicine after the expiry has passed, it may not work as well.

Do not use SAIZEN if the packaging is torn or shows signs

of tampering, or the product does not look quite right.

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

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

Before you start to use it

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

- **Diabetes mellitus**
Somatropin may cause blood sugar levels to increase. If you are diabetic, your doctor will monitor your treatment and may change your treatment for diabetes.
- **Thyroid disorders**
Your doctor may prescribe another hormone to take if you are found to have developed a lack of thyroid hormone.
- **Brain disorders**
If you have other hormone deficiencies due to a previous brain condition, your doctor needs to correct these before starting treatment with SAIZEN.
During treatment with SAIZEN, your doctor will make regular examinations to check that your original brain disorder has not returned.
There is no evidence to suggest that the use of SAIZEN increases the chance of such conditions coming back. However, your doctor may need to stop your SAIZEN treatment if your brain condition returns.

Tell your doctor if you are pregnant or breastfeeding, or plan to become pregnant or start breastfeeding.

Your doctor will discuss with you the risks and benefits of using SAIZEN if you are pregnant or breastfeeding.

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

If you have not told your doctor about any of the above, tell them before you start using SAIZEN.

Taking other medicines

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

It is usually safe to take other medicines with SAIZEN. However, if you are taking corticosteroids, it is important that you tell your doctor. Corticosteroids are used to treat several illnesses including asthma, allergies and rheumatoid arthritis. Corticosteroids might stop SAIZEN from working as well.

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

How to use SAIZEN

SAIZEN therapy should be carried out under the regular guidance of a doctor who is experienced in the diagnosis and management of growth hormone disorders.

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

They may differ from the information contained in this leaflet.

How to inject

SAIZEN is intended for you to inject yourself by subcutaneous (under the skin) injection, preferably in the evening. Your doctor or nurse will instruct and

assist you in learning the techniques for preparing the solution and for self-injection.

Do not attempt self-injection until you are sure of how to do it.

There are two methods for injecting SAIZEN depending on the presentation:

1. Vial of SAIZEN and vial of solvent – using a syringe.
2. Vial of SAIZEN and cartridge of solvent pre-assembled in a reconstitution device (click.easy[®]) – administered using a device.

If your doctor recommends you use a device, follow the instructions for use provided with that device.

Step-by-step instructions for preparing the solution for these two presentations are in the leaflet provided with the medicine (under “Directions for Use”).

Do not inject SAIZEN if it contains particles and is not clear.

Where to inject

The best areas for injection are loose and soft (flabby) skin away from joints and nerves. Use a different injection site each day to lessen the risk of damage to the fat and tissues under the skin.

Prepare the injection site according to the instructions given by your doctor, nurse or pharmacist. Suitable injection sites are:

- Outside the upper arm
- Abdomen (stomach)
- Upper outer buttocks
- Outside of the thigh.

Do not inject into any areas in which you feel lumps, firm knots, depressions or pain. Talk to your doctor or nurse if you experience anything unusual when injecting.

How much to inject

Your doctor will determine your dose and how frequently you inject (3, 6 or 7 times a week). This depends on why you are being

treated with SAIZEN, and your body surface area or body weight.

If you forget to inject it

If you forget a treatment, contact your doctor, nurse or pharmacist for advice. Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering your injection schedule, ask your pharmacist or nurse for some tips.

If you inject too much

Immediately contact your doctor or the Poisons Information Centre (telephone 0800 764 766) if you are concerned that you have given yourself too much SAIZEN.

Injecting too much SAIZEN can lead to changes in blood sugar levels which may cause you to feel shaky and light-headed. If you have these symptoms, contact your doctor immediately.

While you are using SAIZEN

Things you must do

Keep all of your doctor’s appointments so that your progress can be monitored.

Your doctor will also do tests from time to time to check for side effects.

Before starting any new medicine, tell your doctor or pharmacist that you are using SAIZEN.

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

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

Things you must not do

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

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

Do not stop using SAIZEN without telling your doctor.

Do not change the dose unless your doctor tells you to.

Side effects

Tell your doctor as soon as possible if you do not feel well while using SAIZEN.

SAIZEN helps most people needing treatment with growth hormone but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects.

Inform your doctor if you experience any of the following side effects and they worry you:

- Pain, numbness, redness or swelling at the injection site.
- Muscle or joint pain or swelling, stiffness or pins and needles. These side effects are more common in adult patients. They often appear at the start of treatment and are usually temporary.
- Increased thirst, increased need to pass urine, dry mouth or skin (symptoms of high blood sugar levels).
- Extreme tiredness, lethargy, muscle weakness or cramps (symptoms of low levels of thyroid hormone). This can be tested by your doctor and if necessary they will prescribe appropriate treatment.
- Shaking and/or light-headedness (symptoms of low blood sugar levels).

Inform your doctor immediately if you notice any of the following:

- Unexplained limp or hip/knee pain.
- Strong or recurrent headache associated with nausea, vomiting or sight disturbances.

Other side effects not listed above may also occur in some patients. Some side effects may only be found when your doctor does tests from time to time to check your progress.

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

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using SAIZEN

Storage

Before use, store SAIZEN 3 mg in the refrigerator at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light.

Before use, store SAIZEN 8 mg click.easy below 25°C.

Once opened and mixed with solvent, store SAIZEN 3 mg solution in the refrigerator at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light and use within 21 days.

Once opened and mixed with solvent, store SAIZEN 8 mg click.easy solution in the refrigerator at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light and use within 28 days.

Disposal

If you are self-injecting, you should discard all sharps into a disposal unit.

If your doctor tells you to stop using SAIZEN or if it has passed its expiry date, ask your doctor or pharmacist what to do with any syringes that are left over.

Product description

What it looks like

SAIZEN is supplied as a powder for injection with solvent that have to be mixed together (reconstituted) before use.

Two strengths of SAIZEN are available:

- SAIZEN 3 contains 3 mg of human growth hormone (somatropin)
- SAIZEN 8 mg click.easy contains 8 mg of human growth hormone (somatropin)

SAIZEN 3 is available in packs of 1 or 10 vials of powder and a corresponding number of vials of solvent.

SAIZEN 8 mg click.easy is available in packs of 1 or 5 click.easy devices, each containing a vial of medicine and a cartridge of solvent.

Ingredients

Active Ingredient:

- Somatropin (rmc)

SAIZEN 3 powder and solvent also contain:

- Mannitol
- Sodium phosphates
- Sodium chloride
- Benzyl alcohol
- Water for injections

SAIZEN 8 mg click.easy powder and solvent also contain:

- Sucrose
- Phosphoric acid
- Sodium hydroxide
- Meta-cresol
- Water for injections

Manufacturer/Supplier

SAIZEN is manufactured by Merck Serono and supplied in New Zealand by:

Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Auckland

**Australian Registration
Numbers**

SAIZEN 3: AUST R 42232.

SAIZEN 8 mg click.easy:
AUST R 79594

This leaflet was updated in
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Saizen[®]

Somatropin (rmc), recombinant human growth hormone

Directions for Use

Please read the Consumer Medicine Information before use. If your doctor recommends you administer SAIZEN using an injection device, also refer to the instructions for use provided with that device.

There are two methods for injecting SAIZEN depending on the presentation:

1. Vial of SAIZEN and vial of solvent – using a syringe
2. Vial of SAIZEN and cartridge of solvent pre-assembled in a reconstitution device (click.easy[®]) – administered using a device

Preparation of SAIZEN solution

1. Vial of SAIZEN and vial of solvent: using a syringe (like a normal injection)

- Wash your hands with soap and water.
- To dissolve the SAIZEN powder with the solvent provided you will need a 3 mL syringe, a disposable needle (for reconstitution, 21 G) and an alcohol swab. Assemble everything on a clean dry area.
- Attach the 21 G needle to the 3 mL syringe.
- Remove the caps from the powder vial and the solvent vial and wipe the tops clean with an alcohol swab.
- Insert the needle through the rubber stopper of the solvent vial, turn the vial upside down and draw up the required amount of solvent into the syringe.
- Insert the same needle into the SAIZEN powder vial and slowly empty the contents of the syringe into the SAIZEN vial.
- Withdraw the needle and syringe and put into a sharps bin. Dissolve the SAIZEN powder by gently swirling the vial. **AVOID VIGOROUS SHAKING.**
- Using a new needle and syringe (either insulin syringe or 0.5 mL or 1 mL syringe with a 30 G needle) gently push the needle through the rubber stopper, turn the vial upside down and draw up the volume of SAIZEN recommended by your doctor.
- Tap the syringe lightly to remove any air bubbles

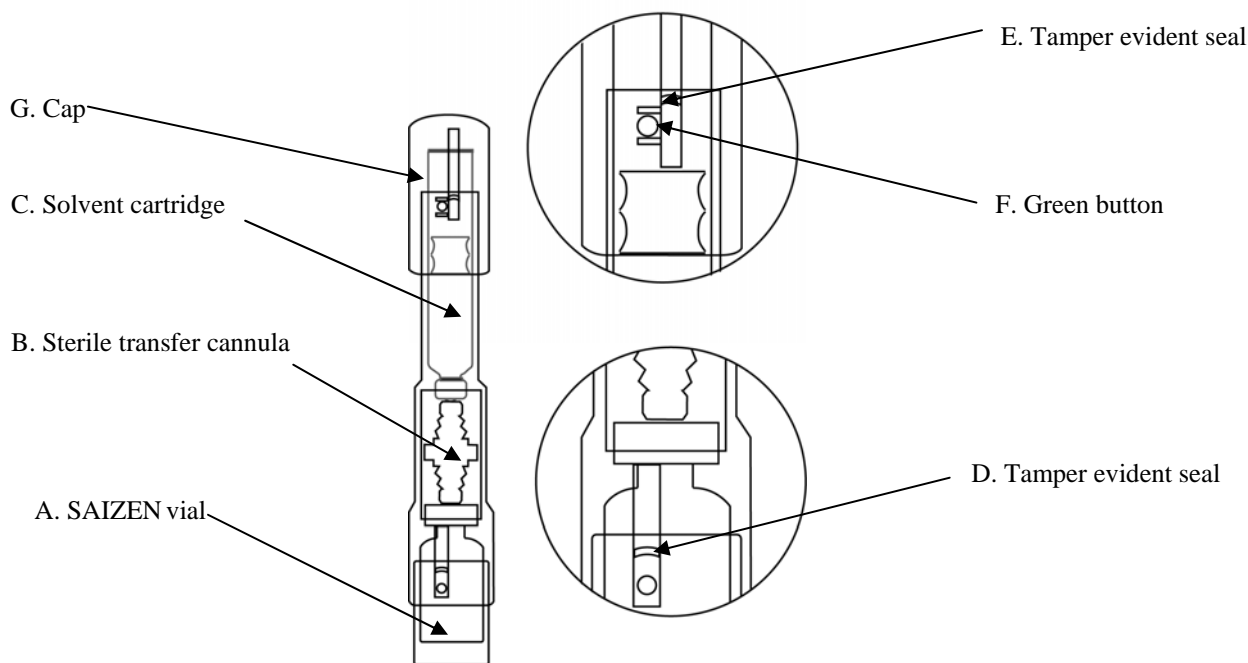
2. Vial of SAIZEN and cartridge of solvent pre-assembled in a click.easy reconstitution device and administered using a device.

Important information on the SAIZEN 8 mg click.easy.

Patients should be thoroughly instructed in the reconstitution procedure.

For young children, the reconstitution process should be supervised by an adult.

- Make sure the click.easy reconstitution device (see diagram below) is complete by checking that the SAIZEN vial (A), the sterile transfer cannula (B) and the solvent cartridge (C) are present.
- Check that the tamper evident seals (D) and (E) are not broken. Check that the green button (F) is not engaged in the vertical opening. If the tamper evident seals are broken or the green button is engaged in the vertical opening, return it to your pharmacist or doctor.
- Wash your hands with soap and water.



How to prepare your solution of SAIZEN 8 mg click.easy:

- 1) Stand the click.easy vertically on a flat and clean surface with the vial (A) at the bottom and the cap (G) facing upward.
- 2) Push the cap down firmly until it will go no further (Note: the tamper evident seal on the click.easy housing (D) is now broken).
- 3) Turn the cap clockwise until the green button (F) is visible in the vertical opening.
- 4) Continue pushing the cap down very slowly, until it will go no further, to transfer the solvent from the cartridge (C) into the vial. (Note: the tamper evident seal (E) is now broken). It is important to push slowly to prevent foam appearing in the vial. Check that all the solvent has been transferred into the vial.
- 5) Dissolve the powder with the solvent by gently swirling the click.easy. (Note: avoid vigorous shaking to prevent creation of foam). Let the solution stand until the powder is completely dissolved.
- 6) Turn the click.easy upside down (vial on top). Push the cap up until it will go no further and subsequently pull the cap slowly downwards until the solution is completely drawn back into the cartridge. Check that no more than one or two drops of solution remain in the vial. If there are more than one or two drops of solution remaining in the vial, slowly push the cap up until some of the solution is back in the vial and gently tap the click.easy. Then draw the solution again slowly back into the cartridge. Remove any excess air that has been drawn into the cartridge by slowly pushing the cap upwards (Note: avoid pulling the cap downwards too fast, as this will draw air into the cartridge).
- 7) Keeping the click.easy in this position (vial on top) unscrew the cap and remove it. Do not pull the cap as this will remove the cartridge stopper. Still keeping the same position (vial on top) remove the cartridge containing the reconstituted solution for injection from the click.easy.
- 8) Carefully peel off the outer label using the tab provided. Write the reconstitution date on the transparent inner label on the cartridge.

Discard the click.easy safely in accordance with your local requirements.

The cartridge containing the reconstitution solution of SAIZEN is now ready to be used for administration.