

SAIZEN®

Somatropin (rhc), recombinant human growth hormone

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 need 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 a genetic condition called gonadal dysgenesis, often referred to as Turner Syndrome, which may cause short stature.
- Growth hormone deficiency in adults.
- Growth disturbance (growth retardation) in pre-pubertal children with chronic renal insufficiency (CRI).

SAIZEN contains somatropin, which is the same as natural human growth hormone, but is made in a laboratory.

If you are unsure as to why you have been prescribed SAIZEN, ask your doctor.

Your doctor may have prescribed it for another reason.

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 have 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.

In children with CRI, treatment with Saizen must be discontinued at the time of renal transplantation.

Do not use SAIZEN 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 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:

- **Any type of cancer**
- **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.

Your SAIZEN treatment may need to be stopped if your brain condition returns.

• **Liver or Kidney disorders**

Your doctor may need to adjust your SAIZEN treatment if you have any pre-existing condition with your liver or kidney.

Treatment with SAIZEN in children with CRI should only be started after growth disturbance has been confirmed over a period of one year or upon your doctors discretion (for example not less than 6 months in older children).

Children with CRI should be examined and monitored regularly for evidence of bone disease. It is uncertain whether the bone disease and its complications are affected by growth hormone therapy.

Assessment of the hip should be obtained prior to initiating therapy and at regular intervals upon discretion of your doctor.

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 him/her before you start using SAIZEN.

Do not use the solvent included in the pack of SAIZEN 3 in children under 3 years old.

If your doctor has prescribed SAIZEN 3 for a younger child, he/she will tell you how to prepare the solution with a different solvent.

Taking other medicines

Tell your doctor if you are taking any other medicines, including:

- All prescription medicines including any hormone

replacement (e.g. oral oestrogen)

- All medicines, vitamins, herbal supplements or natural therapies that you buy without a prescription from your pharmacy, supermarket, naturopath or health food shop.

Tell your doctor if you are taking corticosteroids.

Corticosteroids are used to treat several illnesses including asthma, allergies and rheumatoid arthritis. Corticosteroids might stop SAIZEN from working well.

If you are not sure if you are taking any of these medicines, ask your doctor or pharmacist.

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, nurse or pharmacist will instruct and assist you in learning the techniques for preparing the medicine and for self-injection.

If your doctor has prescribed SAIZEN solution for injection, the medicine is provided in a cartridge with a dedicated autoinjector device (provided separately).

Follow the Instructions for Use provided with the device carefully.

If your doctor has prescribed SAIZEN powder for injection, there are two methods for injecting the medicine depending on the presentation:

1. SAIZEN 3 mg: Vial of SAIZEN and vial of solvent - using a syringe.
2. SAIZEN 8 mg click.easy: 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"). Follow all instructions given to you by your doctor or nurse carefully.

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

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 time 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 of 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, nurse or pharmacist 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 131 126 in Australia or 0800 764 755 in New Zealand) if you are concerned that you or anyone else may have used too much SAIZEN.

If you feel shaky or lightheaded, contact your doctor immediately.

Injecting too much SAIZEN can lead to changes in blood sugar levels.

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 and 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.

Tell 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.
- Headache

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 he/she

will prescribe appropriate treatment.

- Shaking and/or light-headedness (symptoms of low blood sugar levels).
- Tingling, numbness, weakness, or pain in the fingers or hand, or pain in your arm between hand and elbow (symptom of pressure on nerve around your wrist).

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

- Symptoms of an allergic reaction which 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.
- Unexplained limp or hip/knee pain.
- Strong or recurrent headache associated with nausea, vomiting or sight disturbances.

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

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.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using SAIZEN

Storage

SAIZEN powder for injection

SAIZEN 3 mg:

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

Once opened and mixed with solvent, store the SAIZEN 3 mg solution in the refrigerator at 2°C to

8°C (Refrigerate. Do not freeze).

Protect from light.

SAIZEN 8 mg click.easy:

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

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

For both SAIZEN 3 mg and 8mg click.easy, once reconstituted (opened and mixed), follow the instructions on the pack for how long to keep SAIZEN in the refrigerator. It is recommended that you write down the date of reconstitution on the pack so you can check when the solution expires.

SAIZEN injection solution:

Keep SAIZEN injection solution in the original package, in a refrigerator where the temperature is between 2°C to 8°C (Refrigerate. Do not freeze) and it is not exposed to light.

Do NOT store it in the freezer.

SAIZEN injection solution is intended for multiple use in one patient only.

After first injection, store at 2°C to 8°C (Refrigerate. Do not freeze) for a maximum of 28 days, of which up to 7 days can be at or below 25°C. Protect from light. After first injection use within 28 days and discard any leftovers.

SAIZEN cartridge must be used with an autoinjector device.

The autoinjector containing a cartridge of SAIZEN must be stored in the device storage box.

Disposal

Discard all sharps into a disposal unit.

Sharps are objects or devices having sharp points or edges capable of cutting or piercing the skin.

Ask your doctor or pharmacist what to do if you have any

SAIZEN that has expired or is left over from your treatment.

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, or as an injection solution.

SAIZEN powder for injection

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 mg is available in packs 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.

SAIZEN injection solution

SAIZEN injection solution is presented in cartridges for multiple injections in one patient only.

SAIZEN injection solution is registered in three presentations: 6 mg (in 1.03 mL), 12 mg (in 1.5 mL) and 20 mg (in 2.5 mL).

Each presentation is supplied in boxes of 1 cartridge. Your doctor will decide which presentation is suitable for you or your child.

Ingredients

SAIZEN powder for injection

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

SAIZEN injection solution

Active Ingredient:

SAIZEN 6 mg contains somatropin (rmc) 6 mg in 1.03 mL (5.83 mg/mL)

SAIZEN 12 mg contains somatropin (rmc) 12 mg in 1.5 mL (8.00 mg/mL)

SAIZEN 20 mg contains somatropin (rmc) 20 mg in 2.5 mL (8.00 mg/mL)

Other Ingredients:

- Sucrose
- Poloxamer
- Phenol
- Water for injections
- Sodium hydroxide
- Citric acid-anhydrous

Manufacturer/Supplier

Sponsor in Australia:

Merck Serono Australia Pty Ltd
3-4/25 Frenchs Forest Road East
Frenchs Forest NSW 2086

For SAIZEN education and support, call connections for growth on 1800 724 936.

Sponsor in New Zealand:

Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks, Auckland

For any questions about SAIZEN, call Merck Serono Australia Medical Information on + 61 2 8977 4100.

Australian Registration Numbers

SAIZEN 3: AUST R 42232.

SAIZEN 8 mg click.easy: AUST R
79594.

SAIZEN 6 mg: AUST R 166475

SAIZEN 12 mg: AUST R 166478

SAIZEN 20 mg: AUST R 166479.

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