SAIZEN®

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 SAIZEN?

SAIZEN contains the active ingredient somatropin (rmc). 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), growth disturbance in short children born small for gestational age (SGA) who fail to demonstrate catch-up growth by four years of age or later.

For more information, see Section 1. Why am I using SAIZEN? in the full CMI.

2. What should I know before I use SAIZEN?

Do not use if you have ever had an allergic reaction to SAIZEN 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 SAIZEN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SAIZEN and affect how it works.

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 SAIZEN?

- 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.
- Follow the Instructions for Use provided with the device carefully.

More instructions can be found in Section 4. How do I use SAIZEN? in the full CMI.

5. What should I know while using SAIZEN?

Things you should do	• Remind any doctor, dentist, nurse or pharmacist you visit that you are using SAIZEN. • Tell your doctor as soon as possible if you do not feel well while using SAIZEN.
Things you should not do	• Do not stop using this medicine suddenly without telling your doctor. • 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 change the dose unless your doctor tells you to.
Driving or using machines	• Due to its pharmacological profile, somatropin is unlikely to impair patient's ability to drive or to operate machinery.
Looking after your medicine	• 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. • SAIZEN cartridge must be used with an autoinjector device. • The autoinjector containing a cartridge of SAIZEN must be stored in the device storage box.

For more information, see Section 5. What should I know while using SAIZEN? in the full CMI.

6. Are there any side effects?

The most serious side effects include symptoms of allergic reactions (e.g. 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, hip or knee pain and strong or recurrent headache associated with nausea, vomiting or sight disturbances. 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.

SAIZEN®

Active ingredient(s): *somatropin (rmc), recombinant human growth hormone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SAIZEN. **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 SAIZEN.**

Where to find information in this leaflet:

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

1. Why am I using SAIZEN?

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

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), growth disturbance in short children born small for gestational age (SGA) who fail to demonstrate catch-up growth by four years of age or later.

A doctor who is experienced in the diagnosis and management of growth failure or disturbance will assess if you require treatment with SAIZEN.

Your doctor may have prescribed SAIZEN for another reason.

Ask your doctor if you have any questions about why SAIZEN has been prescribed for you.

2. What should I know before I use SAIZEN?

Warnings

Do not use SAIZEN if:

- you are allergic to somatropin, or any of the ingredients listed at the end of this leaflet.
  Always check the ingredients to make sure you can use this medicine.
- 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 such as open-heart surgery or abdominal 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 pharmacists for disposal.

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

Check with 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.
  - scoliosis
    Your doctor needs to monitor for any signs of scoliosis as rapid growth in any child can cause progression of scoliosis.
  - slipped capital femoral epiphysis
    If you or your child experiences difficulty in walking during treatment with SAIZEN, or if you/they complain of your/their joints (hip or knee) and/or start limping, consult your or their doctor immediately. The doctor should make sure that these symptoms are not caused by a displacement of the femoral head in relation to the joint head (so-called epiphysiolysis) or by a circulatory disorder of the femoral head (so-called

Legg-Calve-Perthes disease) before continuing treatment with SAIZEN.

- o 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.

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?

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

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

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

Children with chronic renal insufficiency (CRI)

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 doctor's 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.

Children born small for gestational age (SGA)

Children with SGA should be examined and monitored regularly to check the fasting insulin and blood glucose before starting treatment with SAIZEN and every year.

It is recommended to measure your child's IGF-1 level (Insulin-like Growth Factor 1) before start of treatment and twice a year thereafter.

Your doctor will advise you how to measure your blood sugar and will monitor or perform other tests as required.

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.

Medicines that may <u>reduce</u> the effect of SAIZEN include:

- Corticosteroids

  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.
- Oral estrogen (hormone) replacement medicine

  Tell your doctor if you are using or if you will start to use an oral estrogen (hormone) replacement medicine.

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

4. How do I 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.

How much to take / use

- 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.
- Follow the instructions provided and use SAIZEN until your doctor tells you to stop.

When to take / use SAIZEN

- SAIZEN should be used preferably in the evening.

How to inject

- SAIZEN is intended for you to inject by subcutaneous (under the skin) injection

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

SAIZEN solution for injection is provided in a cartridge with a dedicated autoinjector device (provided separately). The autoinjector device provided with your medicine can either be electronic or hand-operated.

Follow the Instructions for Use provided with the device 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

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.

Talk to your doctor, nurse or pharmacist if you experience anything unusual when injecting.

If you forget to use SAIZEN

SAIZEN should be used regularly at the same time each day. If you miss your dose at the usual time, contact your doctor, nurse or pharmacist for advice.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

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

If you use too much SAIZEN

If you think that you have used too much SAIZEN, 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 SAIZEN?

Things you should do

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

Call your doctor straight away if you:

- Notice 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
- are about to start on taking any new medicines.
- If you become pregnant while using SAIZEN.

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

Things you should not do

- Do not stop using this medicine suddenly without telling your doctor.
- 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 change the dose unless your doctor tells you to.

Driving or using machines

Due to its pharmacological profile, somatropin is unlikely to impair patient's ability to drive or to operate machinery.

Looking after your medicine

- 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 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.
- After first injection, if refrigeration is temporarily unavailable, it can be stored for up to 7 days below 25°C. Protect from light. Following this, it must be returned to the refrigerator and stored at 2°C to 8°C (Refrigerate. Do not freeze) for a maximum of 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.

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

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

Keep it where young children cannot reach it.

When to discard your medicine

Discard all sharps into a disposal unit.

Ask your doctor or pharmacist what to do if you have any SAIZEN that has expired or is left over from your treatment.

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.

Less serious side effects

Less serious side effects	What to do
• Injection site related: o pain, numbness, redness or swelling at the injection site o local fat loss • Muscle or joint related: o pain in muscles or joints o stiffness o swelling of limbs • Infection related: o upper respiratory tract infection o ear infection o chickenpox • Gastrointestinal system related:	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
o inflammation o abdominal pain • Respiratory system related: o inflammation in some parts of the respiratory tract such as pharynx, bronchial tube, tonsils or nose Many of these events reflect commonly observed childhood infections or accidental injuries. **These side effects are more common in adult patients. They often appear at the start of treatment and are usually temporary:** • Metabolism and hormone related: o increased thirst, increased need to pass urine, dry mouth or skin (symptoms of high blood sugar levels) o shaking and/or light-headedness (symptoms of low blood sugar levels) o 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. • Nervous system related: o tingling, numbness, weakness or pain in the fingers or hand, or pain in your arm between hand and elbow (symptoms of pressure on nerve around your wrist). o pins and needles sensation o headache	

Serious side effects

Serious side effects	What to do
Symptoms of allergic reactions: • 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	**Call your doctor immediately, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**
Difficulty in walking, unexplained limp or hip/knee pain **Strong or recurrent headache associated with nausea, vomiting or sight disturbances**	

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 SAIZEN contains

Active ingredient (main ingredient)	Somatropin (rmc)
Other ingredients (inactive ingredients)	Sucrose, poloxamer, phenol, water for injections, sodium hydroxide, citric acid-anhydrous

Do not take this medicine if you are allergic to any of these ingredients.

What SAIZEN looks like

SAIZEN is a solution for injection in a cartridge in three different strengths:

SAIZEN 6 mg contains somatropin (rmc) 6 mg in 1.03 mL (5.83 mg/mL) (AUST R 166475)

SAIZEN 12 mg contains somatropin (rmc) 12 mg in 1.5 mL (8.00 mg/mL) (AUST R 166478)

SAIZEN 20 mg contains somatropin (rmc) 20 mg in 2.5 mL (8.00 mg/mL) (AUST R 166479)

Who distributes SAIZEN

Sponsor in Australia:

Merck Healthcare Pty Ltd

Suite 1, Level 1, Building B

11 Talavera Road

Macquarie Park NSW 2113

Medical Information: 1800 633 463

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

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