

SAIZEN LIQUID

Somatropin (6mg, 12mg, 20mg)

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What Saizen is used for

Saizen is a growth hormone.

In children and adolescents:

- In the treatment of children with short stature who have failed to grow because their body produces no growth hormone or insufficient levels of growth hormone.
- In the treatment of girls who have failed to grow due to gonadal dysgenesis (also referred to as Turner Syndrome), confirmed by a test on the chromosomes.
- In the treatment of growth problems in children who were born small and who have not reached normal height by the age of 4 years or later.

In adults:

- In the treatment of adults with a marked lack of growth hormone (growth hormone deficiency).

This therapy is given to adults who have a serious growth hormone deficiency that has been medically diagnosed by a test.

How Saizen works

Saizen's main action is to increase growth in children and adolescents and to treat adults with growth hormone deficiency. The growth hormone (somatropin) contained in Saizen is almost the same as human's natural growth hormone except that it is made outside the body by a process called "recombinant DNA technology" (genetic engineering).

Before you use Saizen

When you must not take it

- If you or your child are allergic

(hypersensitive) to somatropin or any of the other ingredients of Saizen.

- If you have been told that your child's bones have stopped growing and that he/she has therefore reached his/her final height.
- If you have an active tumour (cancer). Tumours must be inactive and you must have finished your anti- tumour treatment before you start your treatment with Saizen.
- If you or your child have an acute critical illness, suffering complications following open heart surgery, abdominal surgery, multiple accidental trauma, acute respiratory failure or similar conditions.

Before you start to take it

You should inform your doctor or health care professional if you have or had any of the following conditions

- chronic renal failure
- bone disease
- hormone problem

If you take other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

It is important to tell the doctor or pharmacist if you or your child using corticosteroids, sex steroid, anticonvulsant and cyclosporine. These medicines could interact with Saizen and therefore your doctor may need to adjust the dose of these medicines or your Saizen dose.

How to take Saizen

How much to take

Always use Saizen exactly as your doctor has told you. You should consult your doctor or pharmacist if you are not sure.

Children and adolescents:

- Short stature due to a lack of, or insufficient levels of natural growth hormone: 0.7-1.0 mg/m² body surface area each day or

0.025- 0.035 mg/kg body weight each day by subcutaneous administration (under the skin).

- Growth failure in girls due to gonadal dysgenesis (Turner Syndrome): 1.4 mg/m² body surface area per day or 0.045-0.050 mg/kg body weight each day by subcutaneous administration (under the skin).
- If your daughter is treated for Turner Syndrome and she receives non-androgenic anabolic steroids as well, growth response may be enhanced. Ask your doctor or pharmacist if you are not sure about these drugs.
- Growth problems in children who were born small: 0.035 mg/kg body weight (or 1 mg/m²/day, equal to 0.1 IU/kg/day or 3 IU/m²/day) per day, by subcutaneous administration

Adults:

- Growth Hormone Deficiency in adult: At the start, low doses of 0.15-0.30 mg each day to inject subcutaneous are recommended. The dose will be adjusted in stages by your doctor. The recommended final dose of growth hormone rarely exceeds 1.0 mg/day.

In general, the lowest efficacious dose that works for you should be administered. If you are older or overweight, a lower dose may be necessary.

For administration of Saizen Liquid, users must follow the instructions given in the package leaflet and the instruction manual supplied with each auto-injector or injector (cf. 'Instructions for handling'). Injection sites should be varied to prevent localized lipoatrophy.

When to take it

It is recommended that Saizen be administered at bedtime.

The dose and frequency of administration of Saizen will be decided by your doctor and will depend on your or your child's body weight or body surface area.

How long to take it

Your child should stop using this treatment when he or she reaches a satisfactory adult height or his or her bones cannot grow any longer, as assessed by his or her doctor.

If you forget to take it

If you miss a dose, tell your doctor as it may be necessary to slightly change the dose to make up for this.

If you take too much (overdose)

If you inject too much Saizen, you should tell your doctor as it may be necessary to change slightly the dose to make up for this. Injecting too much can lead to changes in blood sugar levels which could mean that you or your child will feel shaky and light-headed. If this happens contact your doctor as soon as possible.

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

While you are using Saizen***Things you must do***

There is currently insufficient evidence from human studies on the safety of growth hormone treatment during pregnancy and breast feeding. Saizen should be discontinued, if pregnancy occurs.

If you become pregnant or are planning to get pregnant tell your doctor immediately. Consult your doctor before taking Saizen if you are breast feeding or about to start breast-feeding.

Thing you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Things to be careful of

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

Somatropin-containing products have no influence on the ability to drive and use machines.

Side effects

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

Visit your doctor **immediately** if you experience any of the following very rare, severe side effects after taking this medicine.

Common:

- Redness and itching at the site of injection
- Swelling
- Muscle pain, joint pain, and joint disorders in adult users.

These side-effects appear usually early in the treatment and are short-lived.

Uncommon:

- Carpal tunnel syndrome that is characterized by persistent stinging, burning sensation, pain and/or numbness in the hand.
- Recurrent headaches associated with feeling sick (nausea), vomiting or sight disturbances.*

Very rare:

- Limbs and hip or knee pain
- Leukemia
- Develop antibodies to somatropin

*These are symptoms of a side effect called benign intracranial hypertension and it is uncommon. Tell your doctor immediately if you experience.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-7883 5490, or visiting the website npra.gov.my [Consumers > Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Saizen***Storage***

Keep out of the reach and sight of children.

Store in a refrigerator (2°C-8°C).

Do not use Saizen after the expiry date which is stated on the cartridge after EXP. The expiry date refers to the last day of that month. After first injection, store in a refrigerator (2°C -8°C) for a maximum of 28 days, of which up to 7 days can be outside of a refrigerator at or below 25°C.

Protect from light.

Do not freeze.

Disposal

If your doctor tells you to stop taking Saizen, or the medicine have passed their expiry date ask your pharmacist how to dispose of medicines that no longer required. Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.

Product description***What it looks like***

Saizen liquid is a clear to slightly opalescent solution for injection in a pre-filled cartridge (type 1 glass) with a plunger stopper (rubber) and a crimp cap (aluminium and rubber).

Pack size:

Saizen Liquid 6 mg: 1 cartridge with 6 mg somatropin.

Saizen Liquid 6 mg: 5 cartridges with 6 mg somatropin.

Saizen Liquid 12 mg: 1 cartridge with 12 mg somatropin.

Saizen Liquid 12 mg: 5 cartridges with 12 mg somatropin.

Saizen Liquid 20 mg: 1 cartridge with 20 mg somatropin.

Saizen Liquid 20 mg: 5 cartridges with 20 mg somatropin. Not all pack sizes may be marketed.

Ingredients

The active substance is somatropin (Recombinant Human Growth Hormone).

The other ingredients are: sucrose, poloxamer 188, phenol, citric acid (for pH adjustment), sodium hydroxide (for pH adjustment), water for injection.

MAL No:

Saizen Liquid 6mg:

MAL14115027AZ

Saizen Liquid 12mg:

MAL14115028AZ

Saizen Liquid 20mg:

MAL14115029AZ

Manufacturer

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Product Registration Holder

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