

SAIZEN[®] INJECTION

Somatropin (3.33mg)

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What Saizen is used for

Saizen is a growth hormone.

In children and adolescents:

- Treatment of children with short stature who have failed to grow because their body produces no growth hormone or insufficient levels of growth hormone.
- 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.
- 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:

- 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 use it

- If you or your child are allergic (hypersensitive) to somatropin or any of the other ingredients of Saizen.
- If you or your child's bones have stopped growing and therefore reached the 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 use it

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

- brain tumor
- growth failure due to genetically confirmed Prader-Willi Syndrome
- diabetes or glucose intolerance
- damage to the retina of the eyes
- thyroid problem
- benign high blood pressure in the skull

If you have increased risk for diabetes mellitus (e.g. familial history of diabetes, obesity, increased body mass index, severe insulin resistance, skin hyperpigmentation), your doctor will plan for oral glucose tolerance testing (OGTT).

Benzyl alcohol as a preservative in bacteriostatic sodium chloride solution may cause toxic reactions and anaphylactoid reactions (life - threatening events that result from an overreactive and misdirected immune response to a substance that is viewed by the body as foreign) in infants and children up to 3 years old and not be given to premature babies or neonates.

- Taking 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 are 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 use Saizen

- How much to use

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 injection (under the skin) or by injecting into the muscle.
- 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 injection (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 medicines.
- 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 injection.

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 used. If you are older or overweight, a lower dose may be necessary.

- Instructions for use/handling

To reconstitute Saizen, inject 5 ml of the bacteriostatic solvent into the vial of Saizen aiming the liquid against the glass wall. Swirl the vial with a gentle rotary motion until the content is dissolved completely. Avoid vigorous shaking. Discard any unused solvent. Injection sites should be varied to prevent localized loss of fatty tissues.

- When to use it

It is recommended that Saizen be used 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 use it

The treatment is generally continued for several years. 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 use 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 use 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. Moreover, somatotropin overdose is likely to cause manifestations of fluid retention.

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

While you are using it

- Things you must do

There is currently insufficient evidence from human studies on the safety of growth hormone treatment during pregnancy and breast feeding. Your doctor will measure growth hormone level before start of treatment and twice a year thereafter. 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

Saizen has no influence on the ability to drive and use machines. You should be alert to the development of a limp or complaints of hip or knee pain in children treated with Saizen.

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 side effects after taking this medicine.

Common:

- Redness and itching at the site of injection
- Swelling
- Muscle pain, joint pain, and stiffness in adults
- Fluid retention
- Tingling sensation on the skin

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: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Saizen

- Storage

Keep out of the reach and sight of children.

Store in a refrigerator (2°C-8°C).

Store in original package.

Store the reconstituted product at 2°C to 8°C in the original package. The reconstituted solution for injection is stable for 14 days.

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

Powder: 1 vial (Type I glass) contains freeze-dried 3.33 mg Somatotropin (r-hGH) with a stopper and blue flip-off cap or aluminium tear strip.

Pack size: 1, 5 and 10's

Not all pack sizes may be marketed.

Saizen is intended for multiple dose use.

- Ingredients

- Active ingredient: Somatotropin

- Inactive ingredients:

Mannitol, Disodium hydrogen phosphate, Sodium dihydrogen phosphate (pH adjustment), benzyl alcohol, sodium chloride (bacteriostatic)

- *MAL Number:*
MAL19930300AZ

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Product Registration Holder

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