

SAIZEN[®] CLICK.EASY INJECTION

Somatropin (8mg)

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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 intracranial hypertension (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).
- 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 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 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.

- 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 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. Your doctor will measure growth hormone level before start of treatment and twice a year thereafter.

- 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.

Do not use any areas in which you feel lumps, firm knots, depressions, or pain; talk to your doctor or pharmacist about anything you find.

- 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 / Vaccines Safety).

Storage and Disposal of Saizen

- Storage

Keep out of the reach and sight of children.

Do not store above 30°C.

Do not freeze. Store in original package.

Store the reconstituted product in a refrigerator (2°C to 8°C).

After reconstitution, the product may be stored for a maximum of 28 days in a refrigerator (2°C to 8°C).

- 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

1 vial of Saizen 8mg and 1 cartridge of bacteriostatic solvent pre-assembled in 1 reconstitution device

Pack size: 1 and 5's

Not all pack sizes may be marketed. Saizen is intended for multiple dose use.

- Ingredients

- Active ingredient: Somatotropin
- Inactive ingredients: Sucrose, Phosphoric acid and Sodium Hydroxide (pH adjustment), Sodium chloride (bacteriostatic)

- MAL Number:

MAL20013357AZ

Manufacturer

Merck Serono S.p.A.
Via delle Magnolie 15 (loc. frazione Zona Industriale)
70026 - Modugno (BA) – Italy

Product Registration Holder

Merck Sdn Bhd (178145-V)

Level 3, Menara Sunway Annexe,
Jalan Lagoon Timur
Bandar Sunway
46150, Petaling Jaya
Selangor Darul Ehsan

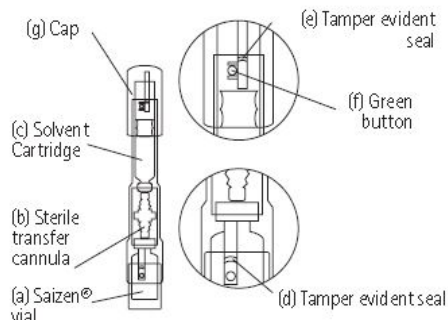
Date of Revision:

10/07/2017

Serial Number

BPFK(R4/1)060717/00167

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



- Make sure the click.easy® 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 on the click.easy® housing (d) and on the cap (e) are not broken. If either of the tamper evident seals are broken return it to your pharmacist or doctor.
 - Place all elements needed for the preparation of the solution on a clean surface.
 - Wash your hands with soap and water.
1. Place the click.easy® reconstitution device vertically on a flat surface with the vial at the bottom and the cap (g) facing upward.
 2. Push the cap down until it will go no further. (Note: The tamper evident seal on the click.easy® housing is now broken).
 3. Turn slightly the cap clockwise until the green button (f) is positioned 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 into the vial (Note: The tamper evident seal on the cap is now broken). It is important to push slowly to prevent foam to appear 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® (Please note that you should not shake the solution strongly

or you will cause the solution to foam). Let the solution stand until the powder is completely dissolved. If the solution contains particles, it must not be injected. Push the cap back down until it will go no further and keep it in position.

6. Turn the click.easy® so that the vial is at the top and 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 slowly again back into the cartridge.

7. Remove any excess air that has been drawn into the cartridge by pushing slowly the cap up until no air is visible in the cartridge. (Note: Avoid pulling the cap down too fast, as this will draw air into the cartridge).

8. Keeping the click.easy® in this position (vial on the top) unscrew the cap and remove it. Still keeping the same position (vial on the top) remove the cartridge containing the reconstituted solution for injection from the click.easy®.

9. 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 reconstituted solution of Saizen® is now ready to be used for injection with your one.click® auto-injector, Easypod® auto-injector or cool.click® needle-free auto-injector.

The reconstituted solution for injection should be clear with no particles. If the solution contains particles, it must not be injected.