

PART III: CONSUMER INFORMATION

PrSAIZEN® 5 mg (Somatropin for injection)

This leaflet is Part III of a three-part “Product Monograph” published when the drug is approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SAIZEN. Contact your health care professional if you have any questions about the drug.

ABOUT THIS MEDICATION

What is SAIZEN?

SAIZEN contains somatropin which is identical to growth hormone found naturally in humans but is made in laboratories.

What is SAIZEN used for?

SAIZEN is indicated for

- the long term treatment of patients with growth failure due to inadequate secretion of growth hormone.
- the treatment of short stature in girls with gonadal dysgenesis (Turner syndrome) when epiphyses are not closed.
- the treatment of growth failure in children due to Chronic Renal Failure.
- growth disturbance (current height Standard Deviation Score (SDS) < -2) in short children born small for gestational age (SGA) with a birth weight and/or length below -2 standard deviations (SD), who failed to show catch-up growth (Height Velocity SDS < 0 during the last year) by 2 years of age or later.
- replacement therapy in adult patients with acquired or idiopathic growth hormone deficiency (GHD) as diagnosed by a single dynamic test for growth hormone deficiency (peak GH $\leq 5 \mu\text{g/L}$).

How SAIZEN works

SAIZEN provides an external supply of human growth hormone for those patients lacking the ability to produce adequate amounts naturally. SAIZEN has many effects on growth and metabolism in patients undergoing therapy;

- stimulates linear growth (growth rate)
- measurable increase in growth (body length) from effects on cartilaginous growth areas of the long bones.
- cellular growth as demonstrated by an increase in the muscular, visceral and red cell mass
- effect on carbohydrate metabolism, including glucose tolerance and insulin levels
- effect on protein metabolism. SAIZEN is an anabolic agent that stimulates intracellular transport of amino acids, net retention of nitrogen and protein synthesis.
- lipid metabolism is also affected when intracellular lipolysis is stimulated, thus increasing the plasma concentration of free fatty acids and stimulating the oxidation of fatty acids.
- connective tissue metabolism is affected by stimulating the synthesis of chondroitin sulfate and collagen as well as the urinary excretion of hydroxyproline

- affects mineral metabolism by inducing the retention of phosphorus and potassium and to a lesser degree sodium.
- also increased are the intestinal absorption of calcium, renal tubular reabsorption of phosphorus with increased serum and inorganic phosphate.

How long is SAIZEN therapy?

Length of time on SAIZEN therapy will vary for every patient. This should be discussed with the patient, parents and doctor throughout the therapy.

Treatment with SAIZEN for growth in children should be discontinued when the patient has reached satisfactory adult height, or the epiphyses (bones) are fused.

When should SAIZEN not be used?

SAIZEN should not be used in the following cases:

- Acute critical illness with complications following cardiac surgery, abdominal surgery, multiple trauma or acute respiratory failure. Clinical studies demonstrated that high doses of another somatropin, were associated with a significantly increased morbidity and mortality in those patients.
- In patients with closed epiphyses, SAIZEN is ineffective for growth. Treatment with SAIZEN should be discontinued when the patient has reached satisfactory adult height, or the epiphyses are fused.
- In the presence of progression of an underlying intracranial tumour. An intracranial tumour should be inactive prior to instituting therapy, and SAIZEN should be discontinued if there is evidence of recurrent activity. Patients should be examined frequently for progression or recurrence of the underlying disease process.
- Patients known to be hypersensitive to somatropin and any of the excipients in powder for solution for injection or the diluent.
- Active neoplasia (either newly diagnosed or recurrent). Any pre-existing neoplasia should be inactive.
- Proliferative or preproliferative diabetic retinopathy.
- In patients with Prader-Willi syndrome who are severely obese or have severe respiratory impairment. Unless patients with Prader-Willi syndrome also have a diagnosis of growth hormone deficiency, SAIZEN is not indicated for long-term treatment of pediatric patients who have growth failure due to genetically confirmed Prader-Willi syndrome.

SAIZEN treatment should be discontinued in critically ill patients.

SAIZEN is not recommended for use during pregnancy and lactation.

In children with chronic renal disease, treatment with somatropin must be discontinued at the time of renal transplantation.

The nonmedicinal ingredients of SAIZEN:

Sucrose, phosphoric acid and sodium hydroxide.

What dosage forms of SAIZEN are available?

SAIZEN is available in a 5 mg vial, with a vial of diluent.

WARNINGS AND PRECAUTIONS

- SAIZEN therapy should be carried out under the regular guidance of a doctor who is experienced in the diagnosis and management of patients with growth hormone deficiency.
- Shortly after SAIZEN is given, the patient may feel shaky or light-headed due to low blood sugar levels. The feelings will quickly disappear. The patient's blood sugar levels may then rise above normal 2-4 hours after administration. Since treatment with growth hormone (GH) can alter how your body handles sugar, the patient's levels will be tested regularly by a health care professional.
- If the patient is diabetic or a member of the family has diabetes, the doctor will monitor closely the treatment with SAIZEN and may change the treatment for diabetes. The doctor may additionally prescribe another hormone if the patient is found to have developed a lack of thyroid hormone.
- If in the past the patient has had a condition affecting the brain e.g. a tumour, the doctor will examine the patient regularly to check that this has not come back again.
- If the patient suffers from a bad or recurrent headache, or from problems with eyesight and vomiting or feeling sick, contact your doctor immediately. Very rarely, a swelling of the brain may develop and the doctor may want to examine the patient's eyes to look for any sign of this. In this case it may be necessary to stop the growth hormone treatment, although the treatment may be re-started at a later date. If the symptoms of brain swelling recur, treatment with SAIZEN should be discontinued.
- When the medicine is injected into the same place over a long time, it can cause damage to this area. It is therefore important to keep changing the injection site. The doctor or nurse can speak to you about which parts of the body should be used.
- Some children with growth hormone deficiency have developed leukemia, whether or not they have received treatment with growth hormone, and might be at a slightly higher risk of developing leukemia than non-growth hormone deficient children. No cause and effect relationship with growth hormone treatment have been proven.
- Hip problems may occur more commonly in children with hormone or kidney problems. If the patient has chronic renal failure (which can occur when kidneys are damaged) he or she should be examined periodically for evidence of bone disease. It is uncertain whether the bone disease in children with hormone or kidney problems is affected by growth hormone therapy. X-rays of the hip should be obtained prior to initiating therapy. If the patient develops a limp or complains of hip or knee pain while being treated with SAIZEN, notify your doctor.
- In children with chronic renal failure, treatment should be discontinued at the time of renal transplant.
- Small for Gestational Age (SGA) patients: SGA means small for gestational age. Gestational age is the time a baby is in its mother's womb. SGA refers to a baby who is smaller than most babies of the same gestational age. Patients who are small for their gestational age have a greater chance of developing diabetes. It is important to have your fasting insulin and blood glucose levels checked before and during treatment with SAIZEN.

MEDICATION INTERACTION

It is usually safe to take other medicines. However, if the patient is taking CORTICOSTEROIDS, it is necessary to tell the doctor or nurse. These medicines are used to treat several illnesses including asthma, allergies, kidney rejection and rheumatoid arthritis. These medicines might stop your growth treatment from working.

You should tell the doctor or nurse about all medicines that the patient is taking, even those obtained without a doctor's prescription.

PROPER USE OF THIS MEDICATION

Dosage

SAIZEN should be injected preferably in the evening. The dosage and administration schedule of SAIZEN will be adapted to the patient's body weight by the doctor according to the following scheme:

- Growth failure due to inadequate endogenous growth hormone secretion: It is recommended that SAIZEN be administered subcutaneously at a dose of 0.2 mg/kg body weight per week. The dosage can be increased to 0.27 mg/kg per week if there is insufficient response to treatment.
- Growth failure in girls due to gonadal dysgenesis (Turner syndrome): It is recommended that SAIZEN be administered subcutaneously at a dose of 0.375 mg/kg body weight per week (optimal dosing 0.32 – 0.375 mg/kg/week). Concomitant therapy with non-androgenic anabolic steroids in patients with Turner syndrome can enhance the growth response.
- Growth failure in children with Chronic Renal Failure: It is recommended that SAIZEN be administered subcutaneously at a dose of 0.35 mg/kg body weight per week.
- Growth disturbance in short children born small for gestational age (SGA): It is recommended that SAIZEN be administered subcutaneously at a dose of 0.47 mg/kg body weight/week.
- Adult Growth Hormone Deficiency: It is recommended that SAIZEN be administered subcutaneously at a dose of 0.005 mg/kg/day at the start of therapy. This dose may be increased after 4 weeks to 0.01 mg/kg/day if well tolerated. The minimum effective dose should be used and dose requirements may decline with age.

Preparing SAIZEN for Administration

Here are the things you will need before you inject SAIZEN:

- 3 alcohol swabs
- Cotton swab
- 3cc syringe & 23 gauge needle for mixing
- BD insulin syringe for injection
- 1 vial of SAIZEN
- Diluent vial (You need this sterile liquid - the diluent - to dissolve the SAIZEN powder and make it injectable.)
- Syringe safety disposal container for used vials and needles

Always use unopened, sterile needles and syringes and keep the needles capped until needed.

TIP: Your doctor or nurse will explain how much diluent to add to the vial of SAIZEN and how much SAIZEN to inject.

Getting Ready to use SAIZEN

1. Begin by choosing a clean flat surface (like a kitchen or bathroom counter).
2. Wash your hands thoroughly with soap and water. This helps prevent infection.
3. Check the expiration date of your SAIZEN.

Drawing Up the Diluent

1. Carefully twist the needle cover off the long needle syringe.
2. Pull out the plunger to the amount recommended by your doctor or nurse. This brings air into the syringe.
3. Remove the flip-off cap from the diluent vial and discard. Wipe the rubber stopper of the vial with an alcohol swab.
4. Hold the vial firmly on the countertop. Put the needle into the stopper of the SAIZEN diluent vial. Push the plunger of the syringe and inject the air into the vial.
5. Turn the vial upside down. Make sure the needle tip stays in the liquid. Pull back on the plunger until the marks on the barrel of the syringe show that the amount of the diluent suggested by your doctor or nurse has been drawn out.
6. If air bubbles appear in the syringe, gently push the plunger into the syringe to send the air into the vial. You may have to tap the syringe lightly so you can push the bubbles out. Draw up more diluent, if needed, until you have the amount your doctor has prescribed.
7. Pull out the needle from the diluent.

Mixing SAIZEN

1. Remove the flip-off cap from the SAIZEN vial and discard. Wipe the rubber stopper of the vial with an alcohol swab.
2. With the same syringe, put the long needle into the stopper of the SAIZEN vial. Gently place the needle tip against the vial wall. Slowly inject the diluent, aiming the stream of diluent at the glass wall of the vial. **DO NOT AIM THE STREAM AT THE WHITE POWDER** at the bottom of the vial.
3. Take out the needle and throw it away in the safety container.
4. Gently swirl (don't shake) the vial until the powder is completely dissolved. The SAIZEN mixture should be clear. If it stays hazy, cloudy or has pieces floating in it after mixing, do not use it.

TIP: If SAIZEN becomes cloudy after mixing, return it to your pharmacist or nurse.

Preparing SAIZEN For Injection

1. Re-wipe the rubber stopper of the SAIZEN vial with an alcohol swab.
2. Pick up the insulin syringe with the short needle and carefully take off the needle cover.
3. Pull out the plunger to the amount recommended by your doctor or nurse. This brings air into the syringe.
4. Slowly insert the needle straight through the center of the rubber stopper of the vial of newly mixed SAIZEN.

Gently push the plunger to inject air into the vial.

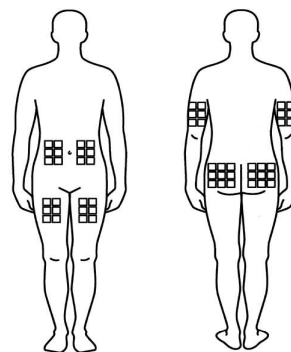
5. Turn the vial upside down with the syringe needle still in it, holding the vial in one hand. Be sure the tip of the needle is in the solution. Using your other hand, slowly pull back on the plunger until the amount of SAIZEN prescribed is in the syringe.
6. Remove the needle from the vial.
7. Hold the syringe straight up and tap gently. Put the plastic needle guard back until injection time. The injection should be given as soon after filling the syringe as possible. Do not store SAIZEN in the syringe.

TIP: Be careful not to touch the uncapped needle with your fingers - or let the needle touch anything.

Picking an Injection Site

You should pick a different site to inject each day, rotating through arms, legs and abdomen. The buttocks can be used, as well (see Injection Site Diagram). Using a site too often can lead to infection or irritation.

Injection Site Diagram



TIP: Many parents find it's a good idea to practice giving injections to each other, so they know what it feels like and to understand their child's reaction better. You can use a small amount of normal saline from the doctor's office.

Injecting SAIZEN

1. Clean the skin at the injection site with an alcohol swab using a circular motion.
TIP: Let the skin dry after cleaning it with alcohol. This helps reduce stinging.
2. Remove the cap from the needle and, using the hand with which you write, pick up the syringe and hold it like a pencil.
3. Pinch up a generous fold of skin and hold it while quickly inserting the needle all the way in at a 90 degree angle to the skin. With your index finger, push the plunger in to inject the medication. Take as much time as you need to inject all the solution. You may wish to count to 5.
TIP: When inserting the needle, you need very little force, but quick action.
4. As you release the skin from your grip, withdraw the needle at the same angle at which it was inserted. Place the cotton swab on the injection site and apply a gentle pressure.

5. Do not put the needle back in the needle guard. Carefully throw away the needle guard and all used needles and syringes in the safety container after a single use.

TIP: NEVER reuse a needle.

Disposal containers must be made of thick, puncture-proof plastic with a lid that fits firmly, such as an empty pop bottle. Containers may be returned to the clinic for disposal or you may wish to contact your pharmacy for further information regarding the safe disposal of used syringes.

Things to remember

1. Make injections routine - give the injection at the same time each evening before bedtime.
2. Store vials at room temperature. However, once reconstituted with bacteriostatic diluent they must be stored in the fridge and may be used for up to 14 days.
3. Check the expiration date.
4. Do not use if it turns cloudy, lumpy or discoloured.
5. Make certain that the dosage is equal to the amount prescribed.
6. Rotate your injection sites each time, as discussed with your nurse.
7. Refrigerate any unused solution.
8. If you are unsure about the mixing of the medication or if you are having difficulty with the injection procedure, contact your nurse or doctor.

What if a Dose is Missed or Too Much is Taken?

If a dose is missed or too much SAIZEN injected it is important to 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 the patient will feel shaky and light-headed. If this happens contact your doctor as soon as possible. If too much were taken over a period in time, this could cause an excessive growth of some bones to occur, particularly the hands, feet and jaw.

There have been no reports of the effects of acute overdose.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with any medicine, side effects can sometimes occur, however most people have no problems with their prescribed SAIZEN. Sometimes, however, redness and itching may appear at the injection site. If this appears to be particularly troublesome, you should discuss this with your doctor.

SAIZEN may bring about insulin resistance. Insulin resistance means your body cannot make good use of the insulin it produces. This causes higher levels of glucose in your blood. Your doctor will need to check your blood glucose on a regular basis. It is also important to check blood glucose if you have diabetes or a family history of diabetes.

Intracranial hypertension is pressure within the skull that is too high. This may be a complication of SAIZEN (growth hormone therapy). Call your doctor if you have a headache that does not go away or goes away and comes back, problems with your vision, a sick feeling in your stomach (nausea) or vomiting.

Very rarely a patient could develop antibodies to somatropin. These are usually not associated with any side effects and do not usually interfere with growth.

If the patient shows an unexplained limp, please contact your doctor or nurse.

If the patient suffers from these or any other unwanted effects, please inform your doctor or nurse.

This is not a complete list of side effects. If the patient experiences any unusual symptom or side effects, you should report them to the doctor immediately. It is also wise to discuss the possibility of side effects with the doctor before beginning treatment.

HOW TO STORE SAIZEN

Lyophilized product:

Store SAIZEN lyophilized product at room temperature.

Do not use SAIZEN after the expiry date shown on label.

Reconstituted product:

SAIZEN 5 mg/vial:

When reconstituted with 1 mL to 3.5 mL Bacteriostatic Water for Injection, USP, the reconstituted solution may be stored at 2-8 °C for up to 14 days.

When reconstituted with Water for Injection, USP, the reconstituted solution should be administered immediately (within 3 hours). Any unused solution should be discarded.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication

Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada.html>); <http://www.emdserono.ca>, or by calling MOMENTUM patient services program at 1-877-724-9361.

This leaflet was prepared by EMD Serono, a business of Merck KGaA, Darmstadt, Germany

Last Revised: April 2020

PART III: CONSUMER INFORMATION

PrSAIZEN® 6 mg (5.83 mg/mL), 12 mg (8 mg/mL), 20 mg (8 mg/mL) cartridges

(Somatropin, Solution for injection in a cartridge)

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SAIZEN is indicated for

- the long term treatment of patients with growth failure due to inadequate secretion of growth hormone.
- the treatment of short stature in girls with gonadal dysgenesis (Turner syndrome) when epiphyses are not closed.
- the treatment of growth failure in children due to Chronic Renal Failure.
- growth disturbance (current height Standard Deviation Score (SDS) < -2) in short children born small for gestational age (SGA) with a birth weight and/or length below -2 standard deviations (SD), who failed to show catch-up growth (Height Velocity SDS < 0 during the last year) by 2 years of age or later.
- replacement therapy in adult patients with acquired or idiopathic growth hormone deficiency (GHD) as diagnosed by a single dynamic test for growth hormone deficiency (peak GH ≤ 5 µg/L).

How SAIZEN works

SAIZEN provides an external supply of human growth hormone for those patients lacking the ability to produce adequate amounts naturally. SAIZEN has many effects on growth and metabolism in patients undergoing therapy;

- stimulates linear growth (growth rate)
- measurable increase in growth (body length) from effects on cartilaginous growth areas of the long bones.
- cellular growth as demonstrated by an increase in the muscular, visceral and red cell mass
- effect on carbohydrate metabolism, including glucose tolerance and insulin levels
- effect on protein metabolism. SAIZEN is an anabolic agent that stimulates intracellular transport of amino acids, net retention of nitrogen and protein synthesis.
- lipid metabolism is also affected when intracellular lipolysis is stimulated, thus increasing the plasma concentration of free fatty acids and stimulating the oxidation of fatty acids.
- connective tissue metabolism is affected by stimulating the synthesis of chondroitin sulfate and collagen as well as the urinary excretion of hydroxyproline

- affects mineral metabolism by inducing the retention of phosphorus and potassium and to a lesser degree sodium.
- also increased are the intestinal absorption of calcium, renal tubular reabsorption of phosphorus with increased serum and inorganic phosphate.

How long is SAIZEN therapy?

Length of time on SAIZEN therapy will vary for every patient. This should be discussed with the patient, parents and doctor throughout the therapy.

Treatment with SAIZEN for growth in children should be discontinued when the patient has reached satisfactory adult height, or the epiphyses (bones) are fused.

When should SAIZEN not be used?

SAIZEN should not be used in the following cases:

- Acute critical illness with complications following cardiac surgery, abdominal surgery, multiple trauma or acute respiratory failure. Clinical studies demonstrated that high doses of another somatropin, were associated with a significantly increased morbidity and mortality in those patients.
- In patients with closed epiphyses, SAIZEN is ineffective for growth. Treatment with SAIZEN should be discontinued when the patient has reached satisfactory adult height, or the epiphyses are fused.
- In the presence of progression of an underlying intracranial tumour. An intracranial tumour should be inactive prior to instituting therapy, and SAIZEN should be discontinued if there is evidence of recurrent activity. Patients should be examined frequently for progression or recurrence of the underlying disease process.
- Patients known to be hypersensitive to somatropin and any of the excipients in powder for solution for injection or the diluent.
- Active neoplasia (either newly diagnosed or recurrent). Any pre-existing neoplasia should be inactive.
- Proliferative or preproliferative diabetic retinopathy.
- In patients with Prader-Willi syndrome who are severely obese or have severe respiratory impairment. Unless patients with Prader-Willi syndrome also have a diagnosis of growth hormone deficiency, SAIZEN is not indicated for long-term treatment of pediatric patients who have growth failure due to genetically confirmed Prader-Willi syndrome.

SAIZEN treatment should be discontinued in critically ill patients.

SAIZEN is not recommended for use during pregnancy and lactation.

In children with chronic renal disease, treatment with somatropin must be discontinued at the time of renal transplantation.

The nonmedicinal ingredients of SAIZEN:

Sucrose, Poloxamer 188, phenol and citric acid.

What dosage forms of SAIZEN are available?

SAIZEN comes as a pre-filled cartridge. There are three presentations which are available:

1. SAIZEN 6 mg with a nominal volume of 1.03 mL of solution. Final concentration that will be injected is 5.83 mg/mL.
2. SAIZEN 12 mg with a nominal volume of 1.50 mL of solution. Final concentration that will be injected is 8 mg/mL.
3. SAIZEN 20 mg with a nominal volume of 2.50 mL of solution. Final concentration that will be injected is 8 mg/mL.

The SAIZEN cartridges are colour coded: SAIZEN 6 mg (5.83 mg/mL) in blue, 12 mg (8 mg/mL) in red, and 20 mg (8 mg/mL) in yellow.

WARNINGS AND PRECAUTIONS

- SAIZEN therapy should be carried out under the regular guidance of a doctor who is experienced in the diagnosis and management of patients with growth hormone deficiency.
- Shortly after SAIZEN is given, the patient may feel shaky or light-headed due to low blood sugar levels. The feelings will quickly disappear. The patient's blood sugar levels may then rise above normal 2-4 hours after administration. Since treatment with growth hormone (GH) can alter how your body handles sugar, the patient's levels will be tested regularly by a health care professional.
- If the patient is diabetic or a member of the family has diabetes, the doctor will monitor closely the treatment with SAIZEN and may change the treatment for diabetes. The doctor may additionally prescribe another hormone if the patient is found to have developed a lack of thyroid hormone.
- If in the past the patient has had a condition affecting the brain e.g. a tumour, the doctor will examine the patient regularly to check that this has not come back again.
- If the patient suffers from a bad or recurrent headache, or from problems with eyesight and vomiting or feeling sick, contact your doctor immediately. Very rarely, a swelling of the brain may develop and the doctor may want to examine the patient's eyes to look for any sign of this. In this case it may be necessary to stop the growth hormone treatment, although the treatment may be re-started at a later date. If the symptoms of brain swelling recur, treatment with SAIZEN should be discontinued.
- When the medicine is injected into the same place over a long time, it can cause damage to this area. It is therefore important to keep changing the injection site. The doctor or nurse can speak to you about which parts of the body should be used.
- Some children with growth hormone deficiency have developed leukemia, whether or not they have received treatment with growth hormone, and might be at a slightly higher risk of developing leukemia than non-growth hormone deficient children. No cause and effect relationship with growth hormone treatment have been proven.
- Hip problems may occur more commonly in children with hormone or kidney problems. If the patient has chronic renal failure (which can occur when kidneys are damaged) he or she should be examined periodically for evidence of bone disease. It is uncertain whether the bone disease in children with hormone or kidney problems is affected by growth hormone therapy. X-rays of the hip should be obtained prior to initiating

therapy. If the patient develops a limp or complains of hip or knee pain while being treated with SAIZEN, notify your doctor.

- In children with chronic renal failure, treatment should be discontinued at the time of renal transplant.
- Small for Gestational Age (SGA) patients: SGA means small for gestational age. Gestational age is the time a baby is in its mother's womb. SGA refers to a baby who is smaller than most babies of the same gestational age. Patients who are small for their gestational age have a greater chance of developing diabetes. It is important to have your fasting insulin and blood glucose levels checked before and during treatment with SAIZEN.

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It is usually safe to take other medicines. However, if the patient is taking CORTICOSTEROIDS, it is necessary to tell the doctor or nurse. These medicines are used to treat several illnesses including asthma, allergies, kidney rejection and rheumatoid arthritis. These medicines might stop your growth treatment from working.

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PROPER USE OF THIS MEDICATION

Dosage

SAIZEN should be injected preferably in the evening. The dosage and administration schedule of SAIZEN will be adapted to the patient's body weight by the doctor according to the following scheme:

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- Growth failure in children with Chronic Renal Failure: It is recommended that SAIZEN be administered subcutaneously at a dose of 0.35 mg/kg body weight per week.
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- Adult Growth Hormone Deficiency: It is recommended that SAIZEN be administered subcutaneously at a dose of 0.005 mg/kg/day at the start of therapy. This dose may be increased after 4 weeks to 0.01 mg/kg/day if well tolerated. The minimum effective dose should be used and dose requirements may decline with age.

Preparing SAIZEN for Administration

SAIZEN 6 mg (5.83 mg/mL), 12 mg (8 mg/mL), 20 mg (8 mg/mL) cartridges

Place all elements needed for the injection of the medication on a clean surface and wash your hands with soap and water. The cartridge containing the medication of SAIZEN is ready to be used for administration with the easypod® electromechanical auto-injector or the aluetta™ pen injector. The solution should be clear to slightly opalescent with no particles. If the solution contains particles, it must not be injected.

The aluetta pen injectors are available in several presentations. Each aluetta pen injector is colour coded and must only be used with the matching colour coded SAIZEN cartridge to give the correct dose:

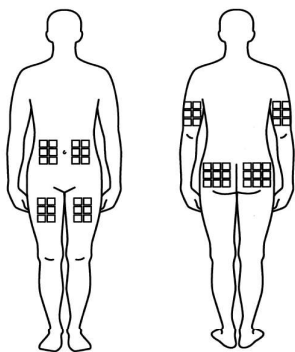
- The aluetta pen injector 6 (blue) must be used with the SAIZEN 6 mg (5.83 mg/mL) cartridge (blue).
- The aluetta pen injector 12 (red) must be used with the SAIZEN 12 mg (8 mg/mL) cartridge (red).
- The aluetta pen injector 20 (yellow) must be used with the SAIZEN 20 mg (8 mg/mL) cartridge (yellow).

For instructions on how to load the cartridge into the easypod electromechanical auto-injector or the aluetta pen injector, please carefully read the corresponding instruction manual provided with the device.

Picking an Injection Site

You should pick a different site to inject each day, rotating through arms, legs and abdomen. The buttocks can be used, as well (see Injection Site Diagram). Using a site too often can lead to infection or irritation.

Injection Site Diagram



What if a Dose is Missed or Too Much is Taken?

If a dose is missed or too much SAIZEN injected it is important to 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 the patient will feel shaky and light-headed. If this happens contact your doctor as soon as possible. If too much were taken over a period in time, this could cause an excessive growth of some bones to occur, particularly the hands, feet and jaw.

There have been no reports of the effects of acute overdose.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with any medicine, side effects can sometimes occur, however most people have no problems with their prescribed SAIZEN. Sometimes, however, redness and itching may appear at the injection site. If this appears to be particularly troublesome, you should discuss this with your doctor.

SAIZEN may bring about insulin resistance. Insulin resistance means your body cannot make good use of the insulin it produces. This causes higher levels of glucose in your blood. Your doctor will need to check your blood glucose on a regular basis. It is also important to check blood glucose if you have diabetes or a family history of diabetes.

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Very rarely a patient could develop antibodies to somatropin. These are usually not associated with any side effects and do not usually interfere with growth.

If the patient shows an unexplained limp, please contact your doctor or nurse.

If the patient suffers from these or any other unwanted effects, please inform your doctor or nurse.

This is not a complete list of side effects. If the patient experiences any unusual symptoms or side effects, you should report them to the doctor immediately. It is also wise to discuss the possibility of side effects with the doctor before beginning treatment.

HOW TO STORE SAIZEN

SAIZEN 6 mg (5.83 mg/mL), 12 mg (8 mg/mL), 20 mg (8 mg/mL) cartridges:

Do not use SAIZEN after the expiry date, which is stated on the cartridge.

Store cartridge(s) in a refrigerator (2-8°C) in the original package.

Do not freeze. Store cartridge(s) in a refrigerator (2-8°C) in the original package.

When using the easypod electromechanical auto-injector or the aluetta pen injector, the cartridge is kept in the device and the device must be stored in the refrigerator.

Do not freeze. After first injection, the cartridges must be stored at 2-8°C for a period of up to 28 days, of which no more than 7 days may be outside of the refrigerator at or below 25°C.

Cartridges must be discarded after 28 days, or if the total period outside of the refrigerator exceeds 7 days.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](https://www.canada.ca/en/health-canada.html) (<https://www.canada.ca/en/health-canada.html>); <http://www.emdserono.ca>, or by calling MOMENTUM patient services program at 1-877-724-9361.

This leaflet was prepared by EMD Serono, a business of Merck KGaA, Darmstadt, Germany.

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