

SCITROPIN A™

Somatropin (rbe) (recombinant human growth hormone, r-hGH)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SciTropin A.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks using this medicine against the benefits they expect it will have for you or your child.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

What SciTropin A is used for

This medicine is used to treat:

- short stature in children due to growth hormone deficiency
- girls with growth disturbance associated with Turner Syndrome
- growth disturbance in children with chronic renal insufficiency.

It contains the active ingredient somatropin. Somatropin is a biosynthetic human growth hormone which is a protein molecule occurring naturally in humans.

SciTropin A is identical to the body's own growth hormone.

Ask your doctor if you have any questions about why this medicine has been prescribed for you or your child.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

Before using SciTropin A

When you must not use it

Do not use this medicine if you have an allergy to:

- somatropin, the active ingredient
- any of other ingredients listed at the end of this leaflet under Product description.

Some of the symptoms of an allergic reaction 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.

Do not use this medicine if you have any of the following medical conditions:

- active tumours or evidence of tumour growth.
- serious injury or illness
- close epiphyses if you are a child (this means that the growth area of the bones is unable to grow anymore).
- are currently being treated for cancer.

Do not give this medicine to child under the age of 3 years.

Do not use this medicine 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 pharmacist for disposal.

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

Before you start to use it

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

Tell your doctor if you have or have had any of the following medical conditions:

- diabetes mellitus
- thyroid disease
- cancer
- any disorder relating to hormones including adrenocortical insufficiency (also known as ACTH deficiency)
- kidney transplant.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start using SciTropin A.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and SciTropin A may interfere with each other. These include:

- corticosteroids used to treat e.g. rheumatoid arthritis, allergic reactions, certain skin conditions and asthma
- some epilepsy medicines, e.g. carbamazepine,
- medicines used to treat diabetes
- thyroid hormone used to treat an underactive thyroid gland
- medicines used to treat Adrenocorticotrophic hormone (ACTH) deficiency, such as hydrocortisone.
- cyclosporin e.g. for the treatment of severe skin disease (psoriasis), rheumatoid arthritis or after transplant surgery
- hormone therapy e.g. hormone replacement therapy (HRT) for oestrogen deficiency, menopause or osteoporosis (bone thinning), testosterone for hormone deficiency in men, or other hormone therapy for contraception ("the Pill"), endometriosis or some cancers.

These medicines may be affected by SciTropin A or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use SciTropin A

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to use

The dose of SciTropin A is different for each person. Your doctor will tell you what the right dose for you or your child is.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to use.

Follow the instructions they give you.

If you use the wrong dose, SciTropin A may not work as well and your problem may not improve.

How to use it

After taking SciTropin A out of the refrigerator allow the glass cartridge to reach room temperature (about 30 minutes) prior to injection.

Reconstitution is not required for SciTropin A Solution for Injection. This medicine is ready-to-use.

Put the glass cartridge containing the SciTropin A solution in the injector pen. Follow the instructions that come with the pen.

Follow the instructions that come with the pen.

When to use SciTropin A

SciTropin A is usually injected once a day in the evening.

How long to use SciTropin A

Continue using your medicine for as long as your doctor tells you.

Your doctor will determine when your treatment should be stopped.

If you forget to use it

Inject your dose as soon as you remember, and continue to inject it as you would normally.

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

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have used too much SciTropin A. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using SciTropin A

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using SciTropin A.

Tell any other doctors, dentists and pharmacists who treat you that you are using this medicine.

If you become pregnant while using this medicine, tell your doctor immediately.

Keep all your doctor's appointments so that your progress can be checked.

Change the site of injection every day.

Inspect the product carefully before use. Only use the injection if the solution is clear. If the solution is cloudy or contains particles, the contents must not be injected.

Things you must not do

Do not use SciTropin A 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. Also do not let anyone use your injector pen.

Do not stop using your medicine or change the dosage without checking with your doctor.

Things to be careful of

Because growth hormone may interfere with your body's use of insulin, you will have to be watchful of glucose intolerance during therapy.

Symptoms of glucose intolerance include increased thirst and need to pass urine.

Follow the instructions for administration of SciTropin A carefully.

Not following instructions might decrease the activity of your medicine or lead to a broken pen injector or cartridge.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using SciTropin A.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- reactions at the injection site, such as bruising, pain, numbness, redness or swelling
- swelling of arms or legs
- joint and/or muscle pain
- stiffness of the hands and feet
- numbness

These are mild side effects of the medicine that usually only occur at the beginning of therapy but also depend on dose.

Tell your doctor as soon as possible if you notice any of the following:

- recurrent headache, blurred vision, nausea and/or vomiting

- increased thirst and need to pass urine, particularly if you are overweight or if anyone in your family has diabetes
- extreme tiredness, lethargy, muscle weakness or change to appetite
- curvature of the spine
- limping or pain in the hip and knee.

The above list includes serious side effects. You or your child may need urgent medical attention or hospitalisation. Serious side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some people.

After using SciTropin A

Storage

Keep your medicine in its original container. If you take it out of its original container it may not keep well.

Keep your medicine in the refrigerator at 2°C to 8°C. Do not freeze.

Keep it where children cannot reach it.

Use an insulated container for transporting your medicine if you are travelling.

Remove the needle from the injector pen after each injection. Return the injector pen with the cartridge to the refrigerator after each use.

If you are using SciTropin A 5mg/1.5mL discard the cartridge 21 days after injecting the first dose.

If you are using SciTropin A 10mg/1.5mL discard the cartridge 28 days after injecting the first dose.

Disposal

Used needles and the empty cartridges should be disposed of in a sharps container or a container composed of hard plastic or glass.

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

SciTropin A Solution for Injection is a clear to colourless solution.

Package Quantities

Each pack of SciTropin A 5mg/1.5mL Solution for Injection contains 1 or 2 cartridges.

Each pack of SciTropin A 10mg/1.5mL Solution for Injection contains 1 or 2 cartridges.

(Pack of 2 cartridges is currently not marketed.)

Ingredients

SciTropin A 5mg/1.5mL Solution for Injection:

- 3.33 mg/mL somatropin (rbe) (active ingredient)
- monobasic sodium phosphate
- dibasic sodium phosphate heptahydrate
- sodium hydroxide
- phosphoric acid
- poloxamer
- mannitol

- water for Injection
- benzyl alcohol (preservative)

SciTropin A 10mg/1.5mL Solution for Injection:

- 6.67 mg/mL somatropin (rbe) (active ingredient)
- monobasic sodium phosphate dibasic sodium phosphate heptahydrate
- poloxamer
- phenol (preservative)
- glycine
- phosphoric acid
- sodium hydroxide
- water for injections

Sponsor

SciGen (Australia) Pty Ltd
4/9 Mogo Place
Billinudgel, NSW 2483
Australia

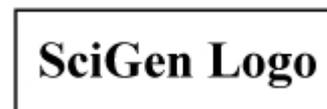
Australian Registration Number

SciTropin A 5 mg/1.5mL Solution for Injection - AUST R 140322

SciTropin A 10 mg/1.5mL Solution for Injection- AUST R 162529

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