SCITROPIN A™

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using SciTropin A?

SciTropin A contains the active ingredient somatropin (rbe). SciTropin A is used to treat short stature in children due to growth hormone deficiency, girls with growth disturbance associated with Turner Syndrome and growth disturbance in children with chronic renal insufficiency.

For more information, see Section 1. Why am I using SciTropin A? in the full CMI.

2. What should I know before I use SciTropin A?

Do not use if you have ever had an allergic reaction to somatropin or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use SciTropin A? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SciTropin A and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I 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.
- You will be taught how to inject SciTropin A before you use it for the first time.
- Follow the instructions that come with the injector pen (pen provided separately).

More instructions can be found in Section 4. How do I use SciTropin A? in the full CMI.

5. What should I know while using SciTropin A?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using SciTropin A. • Call your doctor as soon as possible if you do not feel well while using SciTropin A. • If you become pregnant while using this medicine, tell your doctor immediately.
Things you should 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.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how SciTropin A affects you.
Looking after your medicine	• 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. Protect from light.

For more information, see Section 5. What should I know while using SciTropin A? in the full CMI.

6. Are there any side effects?

Milder side effects that may occur at the beginning of the therapy and are temporary include reactions at the injection site, joint and or muscle pain, muscle stiffness and swelling or numbness in the arms or legs. Side effects such as severe or recurring headaches, blurred vision, nausea or vomiting, swelling of the face, extreme tiredness, change to thirst or appetite, increased need to pass urine, limping, pain in the hip or knee, and curvature of the spine can be serious, and you may need immediate medical attention. These side effects are rare.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

SCITROPIN A™

Active ingredient(s): *somatropin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SciTropin A. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SciTropin A.**

Where to find information in this leaflet:

1. Why am I using SciTropin A?
2. What should I know before I use SciTropin A?
3. What if I am taking other medicines?
4. How do I use SciTropin A?
5. What should I know while using SciTropin A?
6. Are there any side effects?
7. Product details

1. Why am I using SciTropin A?

SciTropin A contains the active ingredient somatropin which is the same as naturally occurring human growth hormone but is made in a laboratory.

SciTropin A 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.

Your doctor may prescribe it for another reason. Ask your doctor if you have any questions about why SciTropin A has been prescribed for you.

2. What should I know before I use SciTropin A?

Warnings

Do not use SciTropin A if:

- you are allergic to somatropin, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

  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.
- you have any of the following medical conditions
  - active tumours or evidence of tumour growth.
  - serious injury or illness, or surgical procedures, requiring intensive care.
  - 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.
  - have Prader-Willi syndrome and are severely overweight or have marked difficulty breathing
  - Do not give this medicine to children under the age of 3 years
- 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.
- you are not sure if you or your child should start using this medicine, talk to your doctor.

Check with your doctor if you:

- have any other medical conditions
  - diabetes mellitus
  - thyroid disease
  - cancer
  - any disorder relating to hormones including adrenocortical insufficiency (also known as ACTH deficiency)
  - kidney transplant.
- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives or dyes

Your doctor should monitor you for glucose intolerance during treatment with Omnitrope. If you are treated with insulin, your doctor may need to adjust your insulin dose.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Use in young children (less in 3 years old)

Do not use more than a week in young children (less than 3 years old) without consulting with your doctor.

SciTropin A 5 mg/1.5 ml solution for injection contains benzyl alcohol.

3. What if I am taking other medicines?

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

In particular, tell your doctor if you are taking

- any medicines (including insulin) for the treatment of diabetes
- corticosteroids such as cortisol or dexamethasone e.g. for the treatment of severe asthma, some skin conditions or rheumatoid arthritis
- some epilepsy medicines, e.g. Carbamazepine, ethosuximide or tiagabine
- thyroxine (thyroid hormone) for treatment of thyroid deficiency
- replacement therapy for Adrenocorticotropic hormone (ACTH) deficiency, such as hydrocortisone or fludrocortisone
- ciclosporin 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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SciTropin A.

4. How do I use SciTropin A?

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 provided and use SciTropin A until your doctor tells you to stop.

When to use SciTropin A

- SciTropin A is usually injected once a day in the evening. Normally, growth hormone is made by the body at night. Giving the injection at night helps to copy this process.

How to use SciTropin A

- Follow all directions given to you by your doctor or pharmacist carefully.
- If you do not understand the instructions, ask your doctor or pharmacist for help.
- SciTropin A is given by injection under the skin (subcutaneous).
- **Change the site of injection every day.**
- **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. This medicine is ready-to-use.
- **Inspect the product carefully before use. Only use the injection if the solution is clear. Do not inject if the solution is cloudy or has particles in it.**
- Put the glass cartridge containing the SciTropin A solution in the injector pen (provided separately).
- Follow the instructions that come with the injector pen.
- Remove the needle from the injector pen after each injection.
- Return the injector pen with the cartridge to the refrigerator after each use.
- Discard the cartridge 28 days after injecting the first dose.

If you forget to use SciTropin A

If you miss your dose at the usual time, inject your dose as soon as you remember, and continue to inject it as you would normally.

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

Do not inject a double dose to make up for the dose 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 SciTropin A

If you think that you have injected too much SciTropin A, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using SciTropin A?

Things you should do

Call your doctor as soon as possible if you experience any of the following:

- rash, wheezing, swelling of the eyelids, face or lips. These may be symptoms of an allergic reaction
- nausea, vomiting, headaches or problems with your vision. These may be symptoms of raised pressure of the fluid around the brain
- limping
- pain in the hips and/or knees

Tell your doctor if you:

- become pregnant while using this medicine
- start to have difficulty breathing or start to snore, or have an increase in snoring while you are using SciTropin A.
- stop or change your oral oestrogen therapy.
- stop or change your glucocorticoid therapy.
- have concerns about how the product looks e.g. if it looks different from normal.

Remind any other doctors, dentists and pharmacists who treat you that you are using Scitropin-A.

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

Things you should not do

- **Do not heat or freeze SciTropin A, it should be stored in the refrigerator at 2-8°C.**
- 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

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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how SciTropin A affects you.

Looking after your medicine

- Keep your medicine in its original container to protect from light. 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.
- Use an insulated container for transporting your medicine if you are travelling.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any 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 can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

side effects	What to do
Administration site disorders: • reactions at the injection site, such as bruising, pain, numbness, redness or swelling • pain or hardness around the injection site **General disorders:** • swelling of arms or legs • swelling of the face **Metabolism and nutrition disorders:** • extreme tiredness, lethargy, muscle weakness or change to appetite • increased thirst and having a dry mouth and skin. Need to pass urine, particularly if you are overweight or if anyone in your family has diabetes • underactive thyroid gland symptoms like cramps, feeling the cold, a slow heart rate, dry and flaky skin, hair loss, a deep and husky voice, weight gain • decreased levels of cortisol **Musculoskeletal disorders:** • curvature of the spine limping or pain in the hip and knee • painful joints and/or muscle aches and pain • Unusual muscle stiffness **Nervous system-disorders:** • nausea and/or vomiting, severe or recurrent headache, or problems with your vision. • tingling or numbness in your fingers, hands or feet **Skin disorders:** • rash, itching or hives on the skin **Reproductive system and breast disorders** • breast enlargement in male	**Speak to your doctor if you have any of these side effects and they worry you.**

There have been very rare reports of leukaemia (a cancer that affects the blood system) developing in children using SciTropin A. A causal association of SciTropin A with the development of leukaemia has not been identified.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What SciTropin A contains

Active ingredient (main ingredient)	Somatropin
Other ingredients (inactive ingredients)	**5 mg/1.5 mL Solution for Injection:** • monobasic sodium phosphate dihydrate • dibasic sodium phosphate heptahydrate • sodium hydroxide • phosphoric acid • poloxamer • mannitol • water for Injection • benzyl alcohol (preservative) **10 mg/1.5 mL Solution for Injection:** • monobasic sodium phosphate dihydrate • dibasic sodium phosphate heptahydrate • poloxamer • phenol (preservative) • glycine • phosphoric acid • sodium hydroxide • water for injections **15 mg/1.5 mL Solution for Injection:** • monobasic sodium phosphate • dibasic sodium phosphate heptahydrate • poloxamer • phenol (preservative) • sodium chloride

	• phosphoric acid • sodium hydroxide • water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What SciTropin A looks like

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

SciTropin A 5 mg/1.5 mL Solution for Injection -

AUST R 140322

- Each pack of SciTropin A 5mg/1.5mL Solution for Injection contains 1, 2, 5* or 10* colourless glass cartridges.

SciTropin A 10 mg/1.5mL Solution for Injection-

AUST R 162529

- Each pack of SciTropin A 10 mg/1.5 mL Solution for Injection contains 1 or 2* colourless glass cartridge.

SciTropin A 15 mg/1.5mL Solution for Injection-

AUST R 484045

- Each pack of SciTropin A 15mg/1.5mL Solution for Injection contains 1 colourless glass cartridge.

*Not marketed in Australia

Who distributes SciTropin A

SciGen (Australia) Pty Ltd

4/9 Mogo Place

Billinudgel, NSW 2483

Australia

Tel: 1800 676 833

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