

SciTropin A™ Cartridge Solution for Injection

Somatropin (5mg/1.5mL (15IU), 10mg/1.5mL (30IU))

What is in this leaflet

1. What SciTropin A™ is used for
2. How SciTropin A™ works
3. Before you use SciTropin A™
4. How to use SciTropin A™
5. While you are using SciTropin A™
6. Side effects
7. Storage and Disposal of SciTropin A™
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What SciTropin A™ is used for

The name of your medicine is SciTropin A™. It contains a biosynthetic human growth hormone known as Somatropin, which is a

protein molecule occurring naturally in humans.

SciTropin A™ is identical to the body's own growth hormone. It is used to treat children who grow too slowly because of a deficiency of growth hormone, chronic renal failure, Prader-Willi syndrome, Turner syndrome, children born small for gestational age and as a replacement therapy in adults with pronounced growth hormone deficiency.

Your doctor, however, may have prescribed SciTropin A™ for another purpose. Ask your doctor if you have any questions about why SciTropin A™ has been prescribed for you.

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

SciTropin A™ is not addictive.

How SciTropin A™ works

SciTropin A™ is produced using recombinant DNA technology. The active substance Somatropin (biosynthetic human growth hormone, rDNA-derived human growth hormone [r-hGH]) is produced in cell culture by Escherichia coli cells bearing the gene for human growth hormone

Before you use SciTropin A™

- When you must not use it

Do not use SciTropin A if:

1. You are allergic to Somatropin or to any of the excipients (benzyl alcohol). Some of the symptoms of an allergic reaction may include skin rash, itching, difficulty breathing or swelling of the face or lips.
2. You have evidence of cancer or tumour.
3. You have a serious injury or illness.
4. The child being treated has closed epiphyses (this means that the growth area of the bones is unable to grow anymore).

The SciTropin A™ 5mg/1.5ml presentation contains benzyl alcohol, its use should be avoided in children under two years of age. Not to be used in neonates.

Do not give this medicine to anyone unless advised by the doctor.

Do not use SciTropin A™ if:

- The packaging is torn or shows signs of tampering.
- The expiry date printed on the pack has passed.

If you are not sure if you or your child should start using SciTropin A™, contact your doctor.

- Before you start to use it

You must tell your doctor if:

1. You are allergic to:
 - Any other medicines
 - Any other substances, such as foods, preservatives or dyes
2. You have or have had any other medical conditions including:
 - Diabetes mellitus
 - Thyroid disease
 - Endocrine disorders
3. You are pregnant or plan to become pregnant.
Your doctor will discuss the risks and benefits of using SciTropin A™ during pregnancy.
4. You are breastfeeding or plan to breastfeed. Your doctor will discuss the risks and benefits of using SciTropin A™ when breast feeding.

If you have not told your doctor about any of the above, tell them before you use any SciTropin A™.

- Taking other medicines

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

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Some medicines may interfere with SciTropin A™. These include:

- Corticosteroids
- Insulin
- Sex Steroids
- Anticonvulsants
- Cyclosporin

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using SciTropin A™.

How to use SciTropin A™

SciTropin A™ is given by injection under the skin (subcutaneous).

SciTropin A™ 5mg/1.5mL and 10mg/1.5mL Solutions for Injection are supplied in glass cartridge. Put the glass cartridge containing the SciTropin A™ solution in the injector pen. Follow the instructions that come with the pen.

Your doctor or nurse will give you appropriate training and instruction on the proper use of SciTropin A™.

It is important that you choose a different injection site every day to prevent unwanted side effects.

: How much to use

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

Do not exceed the recommended dose.

: When to use it

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

: How long to use it

Do not stop using this medicine without first checking with your doctor.

Your doctor will determine when your treatment should be stopped.

: If you forget to use it

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

Otherwise, use it as soon as you remember, and then go back to the normal routine.

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

: If you use too much (overdose)

Immediately telephone your doctor for advice or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have injected 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 it

: Things you must do

Change the site of injection every day.

Use SciTropin A exactly as your doctor has prescribed.

Inspect the product carefully before use. Only use the injection if the solution is clear.

Tell all doctors, dentists and pharmacists who are treating you that you are using SciTropin A.

Tell your doctor immediately if you become pregnant while you are using SciTropin A.

Go to your doctor to have regular check-up.

: Things you must not do

Do not change your dose without first checking with your doctor.

Do not let anyone use your injector pen.

Do not give SciTropin A™ to anyone else, even if their symptoms seem similar to yours.

: 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.

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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.

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

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

- Reactions at the injection site, such as bruise, pain, numbness, redness or swelling
- Disturbances of fluid balance (swelling), joint pain, muscle pain, stiffness of the hands and feet, and numbness

These effects usually occur only at the beginning of therapy but also depend on dose.

Tell your doctor immediately if any of the following side effects occur:

- Recurrent headache, blurred vision, nausea and/or vomiting
- Increased thirst and need to pass urine, particularly if overweight or if anyone in your family has diabetes
- Extreme tiredness, lethargy, muscle weakness, cramps, feeling the cold, a slow heart rate, dry and flaky skin, hair loss, a deep and husky voice and weight gain
- Limping or pain in the hip and knee

These are very serious side effects. You or your child may need urgent medical attention or hospitalization. All of these side effects are very rare.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making your child feel unwell.

Do not be alarmed by this list of possible side effects. You or your child may not experience any of them.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [*Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)*]

Storage and Disposal of SciTropin A™

: Storage

SciTropin A™ 5mg/1.5mL and 10mg/1.5mL Solutions for Injection

- If unopened, keep your medicine in its original container, in a safe place out of the reach of children in a refrigerator at 2°C to 8°C. Do not freeze.
- Return the injector pen with the cartridge to the refrigerator at 2°C to 8°C after each use. Protect from light. Discard the cartridge 28 days after injecting the first dose.

Use an insulated container for transporting the package(s) if you are travelling.

Do not store your medicine in the bathroom or near a sink. Heat and dampness can destroy some medicines.

Do not leave your medication in a car or on a windowsill.

: Disposal

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

If your doctor tells you to stop using SciTropin A™ or the medicines have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product Description

: What it looks like

SciTropin A™ Solution for injection is a clear, colourless solution

: Ingredients

: Active ingredient(s)
Somatropin

: Inactive ingredients
SciTropin A 5mg/1.5ml (15 IU) Cartridge Solution for Injection
sodium phosphate dibasic heptahydrate,
sodium phosphate monobasic dihydrate,
poloxamer,
benzyl alcohol,
mannitol,
water for injection

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SciTropin A 10mg/1.5ml (30 IU)

Cartridge Solution for Injection

sodium phosphate dibasic

heptahydrate,

sodium phosphate monobasic

dihydrate,

poloxamer,

phenol,

glycine

water for injection

Date of revision

March 2025

Serial Number

NPRA (R3/01) 05112024/0322

: *MAL number:*

SciTropin A 5mg/1.5ml (15 IU)

Cartridge Solution for Injection

MAL20102067AZ

SciTropin A 10mg/1.5ml (30 IU)

Cartridge Solution for Injection

MAL20102068AZ

Manufacturer

Novartis Pharmaceutical

Manufacturing GmbH

Biochemiestraße 10

6336 Langkampfen, Austria

For

SciGen Pte. Ltd.

150 Beach Road, #32-05/08 Gateway

West, Singapore 189720

Product Registration Holder

DKSH Malaysia Sdn Bhd

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