

SciTropin A™

SciTropin A 5mg/1.5mL Solution for Injection

SciTropin A 10mg/1.5mL Solution for Injection

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What SciTropin A is and what it is used for
2. What you need to know before you use SciTropin A
3. How to use SciTropin A
4. Possible side effects
5. How to store SciTropin A
6. Contents of the pack and other information

1. What SciTropin A is and what it is used for

SciTropin A is a recombinant human growth hormone (also called somatropin). It has the same structure as natural human growth hormone which is needed for bones and muscles to grow. It also helps your fat and muscle tissues to develop in the right amounts. It is recombinant meaning it is not made from human or animal tissue.

SciTropin A is used to treat children who grow too slowly because of a deficiency of growth hormone or Turner syndrome, 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

You should only be given this medicine by a doctor who has experience with growth hormone treatment and who has confirmed your diagnosis.

2. What you need to know before you use SciTropin A

Do not use SciTropin A if

- if you are allergic (hypersensitive) to somatropin or to any of the other ingredients of SciTropin A.
- 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 SciTropin A.
- if SciTropin A has been prescribed to stimulate growth but you have already stopped growing (closed epiphyses).
- if you are seriously ill (for example, complications following open heart surgery, abdominal surgery, accidental trauma, acute respiratory failure, or similar conditions). If you are about to have, or have had, a major operation, or go into hospital for any reason, tell your doctor and remind the other doctors you are seeing that you use growth hormone.

Warnings and precautions

Talk to your doctor before using SciTropin A.

- If you have a replacement therapy with glucocorticoids, you should consult your doctor regularly, as you may need adjustment of your glucocorticoid dose.
- If you are at risk of developing diabetes, your doctor will need to monitor your blood sugar level during therapy with somatropin.
- If you have diabetes, you should closely monitor your blood sugar level during treatment with somatropin and discuss the results with your doctor to determine whether you need to change the dose of your medicines to treat diabetes.
- After starting somatropin treatment some patients may need to start thyroid hormone replacement.
- If you are receiving treatment with thyroid hormones it may become necessary to adjust your thyroid hormone dose.
- If you have raised intracranial pressure (which causes symptoms, such as strong headache, visual disturbances or vomiting) you should inform your doctor about it.
- If you walk with a limp or if you start to limp during your growth hormone treatment, you should inform your doctor.
- If you are receiving somatropin for growth hormone deficiency following a previous tumour (cancer), you should be examined regularly for recurrence of the tumour or any other cancer.
- If you experience worsening abdominal pain you should inform your doctor.
- Experience in patients above 80 years is limited. Elderly persons may be more sensitive to the action of somatropin, and therefore may be more prone to develop side effects.
- There may be an increased risk of developing an inflammation of the pancreas (pancreatitis) in children compared to adults treated with somatropin. Although rare, pancreatitis should be considered in somatropin-treated children who develop abdominal pain. Contact your doctor if you or your child develops stomach ache, or severe pain in the abdomen and back, after taking SciTropin A.
- An increase in sideways curvature of the spine (scoliosis) may progress in any child during rapid growth. During treatment with somatropin, your doctor will check you (or your child) for signs of scoliosis.

Other medicines and SciTropin A

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

In particular, inform your doctor if you are taking or have recently taken any of the following medicines. Your doctor may need to adjust the dose of SciTropin A or of the other medicines:

- medicine to treat diabetes,
- thyroid hormones,
- medicines to control epilepsy (anticonvulsants),
- ciclosporin (a medicine that weakens the immune system after transplantation),
- oestrogen taken orally or other sex hormones,
- synthetic adrenal hormones (corticosteroids).

Your doctor may need to adjust the dose of these medicines or the dose of somatropin.

Pregnancy and breast-feeding

You should not use SciTropin A if you are pregnant or trying to become pregnant.

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. This is because benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

Important information about some of the ingredients of SciTropin A

SciTropin A 5mg/1.5ml Solution for Injection

This medicine contains less than 1 mmol sodium (23 mg) per ml, i.e. essentially ‘sodium-free’.

This medicine contains 9mg, benzyl alcohol in each ml. Benzyl alcohol may cause allergic reactions.

Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called “gasping syndrome”) in young children.

Do not give to your premature baby and newborn baby (up to 4 weeks old) due to the presence of benzyl alcohol.

Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist, as it may cause toxic reactions and allergic reactions in infants and children up to 3 years old.

SciTropin A 10mg/1.5ml Solution for Injection

This medicine contains less than 1 mmol sodium (23 mg) per ml, i.e. essentially ‘sodium-free’

3. How to use SciTropin A

Always use this medicine exactly as your doctor or pharmacist or nurse has told you. Check with your doctor, nurse or pharmacist if you are not sure.

The dose depends on your size, the condition for which you are being treated and how well growth hormone works for you. Everyone is different. Your doctor will advise you about your individualised dose of SciTropin A in milligrams (mg) from either your body weight in kilograms (kg) or your body surface area calculated from your height and weight in square metres (m²), as well as your treatment schedule. Do not change the dosage and treatment schedule without consulting your doctor.

Injecting SciTropin A

Inject your growth hormone at about the same time every day. Bedtime is a good time because it is easy to remember. It is also natural to have a higher level of growth hormone at night.

SciTropin A is intended for multiple use. It should only be administered with the Pen recommended by your doctor, nurse or pharmacist.

SciTropin A is intended for subcutaneous use. This means that it is injected through a short injection needle into the fatty tissue just under your skin. Most people do their injections into their thigh or their bottom. Do your injection in the place you have been shown by your doctor. Fatty tissue of the skin can shrink at the site of injection. To avoid this, use a slightly

different place for your injection each time. This gives your skin and the area under your skin time to recover from one injection before it gets another one in the same place.

Your doctor should have already shown you how to use SciTropin A. Always inject SciTropin A exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How to inject SciTropin A

The following instructions explain how to inject SciTropin A yourself. Please read the instructions carefully and follow them step by step. Your doctor will show you how to inject SciTropin A. Do not attempt to inject unless you are sure you understand the procedure and requirements for the injection.

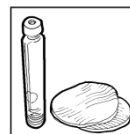
SciTropin A is given as an injection under the skin.

- Carefully inspect the solution before injecting it and use only if clear and colourless.
- Change the injection sites to minimise the risk of local lipoatrophy (local reduction of fatty tissue under the skin).

Preparation

Collect necessary items before you begin:

- a cartridge with SciTropin A solution for injection.

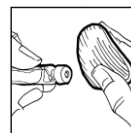


- an injection device recommended by your doctor, pharmacist or nurse (not supplied in the pack; see Instructions for Use provided with the device).
- a pen needle for subcutaneous injection (not supplied in the pack).
- 2 cleansing swabs (not supplied in the pack).

Wash your hands before you continue with the next steps.

Injecting SciTropin A

- With a cleansing swab, disinfect the rubber membrane of the cartridge.
- The contents must be clear and colourless.



- Insert the cartridge into the pen for injection. Follow the Instructions for Use of the pen injector. To setup the pen dial the dose.
- Select the site of injection. The best sites for injection are tissues with a layer of fat between skin and muscle, such as the thigh or belly (except the navel or waistline).
- Make sure you inject at least 1 cm from your last injection site and that you change the places where you inject, as you have been taught.
- Before you make an injection, clean your skin well with an alcohol swab. Wait for the area to dry.



- Insert the needle into the skin in the way your doctor has taught you.

After injecting

- After injection, press the injection site with a small bandage or sterile gauze for several seconds. Do not massage the injection site.
- Take the needle off the pen using the outer needle cap, and discard the needle. This will keep the SciTropin A solution sterile and prevent leaking. It will also stop air going back into the pen and the needle clogging up. Do not share your needles. Do not share your pen.
- Leave the cartridge in the pen, put the cap on the pen, and store it in the refrigerator.
- The solution should be clear after removal from the refrigerator. **Do not use if the solution is cloudy or contains particles.**

If you use more SciTropin A than you should

If you inject much more than you should, contact your doctor or pharmacist as soon as possible. Your blood sugar level could fall too low and later rise too high. You might feel shaky, sweaty, sleepy or “not yourself”, and you might faint.

If you forget to use SciTropin A

Do not use a double dose to make up for a forgotten dose. It is best to use your growth hormone regularly. If you forget to use a dose, have your next injection at the usual time the next day. Keep a note of any missed injections and tell your doctor at your next check-up.

If you stop using SciTropin A

Ask for advice from your doctor before you stop using SciTropin A. If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The very common and common side effects in adults may start within the first months of treatment and may either stop spontaneously or if your dose is reduced.

Very common side effects (may affect more than 1 in 10 people) include:

- Joint pain
- Water retention (which shows as puffy fingers or swollen ankles, for a short time at the start of treatment)
- Reddening, itchiness or pain at the injection site

Common side effects (may affect up to 1 in 10 people) include:

- Numbness/tingling
- Stiffness in the arms and legs, muscle pain

In adults

- Pain or burning sensation in the hands or underarms (known as Carpal Tunnel syndrome)

Uncommon side effects (may affect up to 1 in 100 people) include:

- Breast enlargement
- Itching

Rare side effects (may affect up to 1 in 1,000 patients) include:**In children**

- Leukaemia (This has been reported in a small number of growth hormone deficiency patients, some of whom have been treated with somatropin. However, there is no evidence that leukaemia incidence is increased in growth hormone recipients without predisposing factors.)
- Increased intracranial pressure (which causes symptoms, such as strong headache, visual disturbances or vomiting)

Not known (frequency cannot be estimated from the available data):

- Type 2 diabetes
- A decrease in the levels of the hormone Cortisol in your blood
- Facial swelling
- Headache
- Hypothyroidism

In adults

- Increased intracranial pressure (which causes symptoms such as strong headache, visual disturbances or vomiting)

Formation of antibodies to the injected growth hormone but these do not seem to stop the growth hormone from working.

The skin around the injection area can get uneven or lumpy, but this should not happen if you inject in a different place each time.

There have been rare cases of sudden death in patients with Prader-Willi syndrome.

Slipped capital femoral epiphysis and Legg-Calvé-Perthes disease may be considered by your doctor if discomfort or pain in the hip or knee is experienced whilst being treated with SciTropin A.

Other possible side effects related to your treatment with growth hormone may include the following:

You (or your child) may experience a high blood sugar or reduced levels of thyroid hormone. This can be tested by your doctor and if necessary your doctor will prescribe the adequate treatment. Rarely, an inflammation of the pancreas has been reported in patients treated with growth hormone.

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store SciTropin A

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

- Store and transport refrigerated (2°C–8°C).
- Do not freeze.
- Store in the original package in order to protect from light.
- After the first injection, the cartridge should remain in the pen injector and has to be stored in a refrigerator (2°C–8°C) and only used for a maximum of 28 days.

Do not use SciTropin A if you notice that the solution is cloudy.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What SciTropin A 5mg/1.5mL Solution for Injection Contains

The active substance of SciTropin A is somatropin.

Each ml of solution contains 3.3 mg of somatropin (corresponding to 10 IU)

One cartridge contains 5.0 mg (corresponding to 15 IU) of somatropin in 1.5 ml.

The other ingredients are:

- disodium hydrogen phosphate heptahydrate
- sodium dihydrogen phosphate dihydrate
- mannitol
- phosphoric acid
- poloxamer 188
- sodium hydroxide
- benzyl alcohol
- water for injections

What SciTropin A 10mg/1.5mL Solution for Injection contains

The active substance of SciTropin A is somatropin.

Each ml of solution contains 6.7 mg of somatropin (corresponding to 20 IU)

One cartridge contains 10.0 mg (corresponding to 30 IU) of somatropin in 1.5 ml.

The other ingredients are:

- disodium hydrogen phosphate heptahydrate
- sodium dihydrogen phosphate dihydrate
- glycine
- phosphoric acid
- poloxamer 188
- sodium hydroxide
- phenol
- water for injections

What SciTropin A looks like and contents of the pack

SciTropin A is a clear and colourless solution for injection.

Pack size of 1.

Manufactured by:

Sandoz GmbH
Plant Schafftenau
Biochemiestrasse 10
A-6336 Langkampfen
Austria

Secondary Packager:

Bollore Logistics Singapore Pte Ltd
101 Alps Avenue #03-01
Singapore 498793

For SciGen Pte. Ltd.
150 Beach Road,
#32-05/08 Gateway West,
Singapore 189720

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