SciTropin A™

1. NAME OF THE MEDICINAL PRODUCT

SciTropin A™ Solution for Injection 5 mg/1.5 mL
SciTropin A™ Solution for Injection 10 mg/1.5 mL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

SciTropin A™ Solution for Injection 5 mg/1.5 mL

Each mL of solution contains 3.3 mg of somatropin* (corresponding to 10 IU)
One cartridge contains 1.5 mL corresponding to 5 mg somatropin* (15 IU).
Excipient(s) with known effect:
This medicine contains 9 mg of benzyl alcohol in each mL. Benzyl alcohol may cause allergic reactions.

SciTropin A™ Solution for Injection 10 mg/1.5 mL
Each mL of solution contains 6.7 mg of somatropin* (corresponding to 20 IU)
One cartridge contains 1.5 mL corresponding to 10 mg somatropin* (30 IU).
*produced in *Escherichia coli* by recombinant DNA technology.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
The solution is clear and colourless.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Children
Growth disturbance due to insufficient secretion of growth hormone (growth hormone deficiency, GHD) Growth disturbance associated with Turner syndrome

Adults
Replacement therapy in adults with growth hormone deficiency.

4.2 Posology and method of administration

Diagnosis and therapy with somatropin should be initiated and monitored by physicians who are appropriately qualified and experienced in the diagnosis and management of patients with the therapeutic indication of use.

Posology
Paediatric population
The posology and administration schedule should be individualized.

Indication	mg/kg body weight dose per day	IU/kg body weight	mg/m² body surface area dose per day	IU/m² body surface area
Growth hormone deficiency	0.025-0.035	0.075-0.106	0.7-1.0	2.12-3.03
Turner Syndrome	0.045-0.050	0.136	1.4	4.24

Growth hormone-deficient adult patients
Therapy should start with a low dose, 0.15 - 0.3 mg (0.45 to 0.90 IU) per day. The final dose should be individually titrated as needed with respect to age and gender. The daily maintenance dose seldom exceeds 1.00 mg (3.03 IU) per day. A woman may require higher doses than men. This means that there is a risk that women, especially those on oral estrogen replacement are under-treated. As normal physiological growth hormone production decreases with age, dose requirements may be reduced. Clinical response, side effects, and determination of IGF-1 in serum may be used as guidance for dose titration.

Method of administration
The injection should be given subcutaneously, and the site varied to prevent lipoatrophy. For instructions for use and handling see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Somatropin must not be used when there is any evidence of activity of a tumour. Intracranial tumours must be inactive and anti-tumour therapy must be completed prior to starting GH therapy. Treatment should be discontinued if there is evidence of tumour growth.

Somatropin must not be used for growth promotion in children with closed epiphyses.

Somatropin should not be used in children with PWS and a corresponding severe respiratory disorder or severe obesity.

Patients with acute critical illness suffering complications following open heart surgery, abdominal surgery, multiple accidental trauma, acute respiratory failure or similar conditions must not be treated with somatropin.

In new-borns, SciTropin A™ 5mg/1.5mL Solution for Injection should not be used because of the presence of the preservative, benzyl alcohol.

4.4 Special warnings and precautions for use

The maximum recommended daily dose should not be exceeded (see section 4.2).

Traceability
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Hypoadrenalism
Introduction of somatropin treatment may result in inhibition of 11βHSD-1 and reduced serum cortisol concentrations. In patients treated with somatropin, previously undiagnosed central (secondary) hypoadrenalism may be unmasked and glucocorticoid replacement may be required. In addition, patients treated with glucocorticoid replacement therapy for previously diagnosed hypoadrenalism may require an increase in their maintenance or stress doses, following initiation of somatropin treatment (see section 4.5).

Use with oral oestrogen therapy
If a woman taking somatropin begins oral oestrogen therapy, the dose of somatropin may need to be increased to maintain the serum IGF-1 levels within the normal age-appropriate range. Conversely, if a woman on somatropin discontinues oral oestrogen therapy, the dose of somatropin may need to be reduced to avoid excess of growth hormone and/or side effects (see section 4.5).

Insulin sensitivity
Somatropin may reduce insulin sensitivity. For patients with diabetes mellitus, the insulin dose may require adjustment after somatropin therapy is instituted. Patients with diabetes, glucose intolerance, or additional risk factors for diabetes should be monitored closely during somatropin therapy.

Thyroid function
Growth hormone increases the extrathyroidal conversion of T4 to T3 which may result in a reduction in serum T4 and an increase in serum T3 concentrations. Whereas peripheral thyroid hormone levels have remained within the reference ranges for healthy subjects, hypothyroidism theoretically may develop in subjects with subclinical hypothyroidism. Consequently, monitoring of thyroid function should therefore be conducted in all patients. In patients with hypopituitarism on standard replacement therapy, the potential effect of growth hormone treatment on thyroid function must be closely monitored.

Neoplasms
In growth hormone deficiency secondary to treatment of malignant disease, it is recommended to pay attention to signs of relapse of the malignancy. In childhood cancer survivors, an increased risk of a second neoplasm has been reported in patients treated with somatropin after their first neoplasm. Intracranial tumours, in particular meningiomas, in patients treated with radiation to the head for their first neoplasm, were the most common of these second neoplasms.

Slipped capital femoral epiphysis

In patients with endocrine disorders, including growth hormone deficiency, slipped epiphyses of the hip may occur more frequently than in the general population. Patients limping during treatment with somatropin should be examined clinically.

Benign intracranial hypertension
In case of severe or recurrent headache, visual problems, nausea and/or vomiting, a fundoscopy for papilloedema is recommended. If papilloedema is confirmed, a diagnosis of benign intracranial hypertension should be considered and, if appropriate, the growth hormone treatment should be discontinued. At present there is insufficient evidence to give specific advice on the continuation of growth hormone treatment in patients with resolved intracranial hypertension. If growth hormone treatment is restarted, careful monitoring for symptoms of intracranial hypertension is necessary.

Leukaemia
Leukaemia 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 predisposition factors.

Antibodies
A small percentage of patients may develop antibodies to SciTropin A™. SciTropin A™ has given rise to the formation of antibodies in approximately 1% of patients. The binding capacity of these antibodies is low and there is no effect on growth rate. Testing for antibodies to somatropin should be carried out in any patient with otherwise unexplained lack of response.

Pancreatitis
Although rare, pancreatitis should be considered in somatropin-treated patients who develop abdominal pain, especially in children

Scoliosis
Scoliosis is known to be more frequent in some of the patient groups treated with somatropin. In addition, rapid growth in any child can cause progression of scoliosis. Somatropin has not been shown to increase the incidence or severity of scoliosis. Signs of scoliosis should be monitored during treatment.

Elderly patients

Experience in patients above 80 years is limited. Elderly patients may be more sensitive to the action of SciTropin A™, and therefore may be more prone to develop adverse reactions.

Acute critical illness

The effects of somatropin on recovery were studied in two placebo-controlled trials involving 522 critically ill adult patients suffering complications following open heart surgery, abdominal surgery, multiple accidental trauma or acute respiratory failure. Mortality was higher in patients treated with 5.3 or 8 mg somatropin daily compared to patients receiving placebo, 42% vs. 19%. Based on this information, these types of patients should not be treated with somatropin. As there is no information available on the safety of growth hormone substitution therapy in acutely critically ill patients, the benefits of continued treatment in this situation should be weighed against the potential risks involved. In all patients developing other or similar acute critical illness, the possible benefit of treatment with somatropin must be weighed against the potential risk involved.

Carcinogenesis, mutagenesis, impairment of fertility

Somatropin raises the serum levels of IGF-1. Associations between elevated serum IGF-1 concentrations and risks of certain cancers have been reported in epidemiological studies. Causality has not been demonstrated. The clinical significance of these associations, especially for subjects treated with somatropin who do not have growth hormone deficiency and who are treated for prolonged periods, is not known. Serum IGF-1 levels can be affected by factors other than growth hormone status including nutrition.

Switching of product during therapy

Switching of one somatropin product with another during treatment increases the risk of immunogenic reactions. If such switching is deemed necessary, it should be done with caution and under strict medical supervision.

Benzyl alcohol

Because of the presence of benzyl alcohol in the 15 IU solution for injection, the product must not be given to premature babies or neonates. It may cause toxic reactions and anaphylactoid reactions in infants and children up to 3 years old.

SciTropin A Solution for Injection 5 mg/1.5 ml contains 9 mg of benzyl alcohol in each ml. Benzyl alcohol may cause allergic reactions.

Intravenous administration of benzyl alcohol has been associated with serious adverse events and death in neonates (“gasping syndrome”). The minimum amount of benzyl alcohol at which toxicity may occur is not known.

Advise the parents or legal guardian to not use more than a week in young children (less than 3 years old) without a physician or pharmacist permission.

Advise pregnant or breast feeding patients that large amounts of benzyl alcohol can be build up in their body and may cause sides effects (called “metabolic acidosis”).

Advise patients who have a liver or kidney disease that large amounts of benzyl alcohol can be build up in their body and may cause sides effects (called “metabolic acidosis”).

Sodium content

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

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant treatment with glucocorticoids inhibits the growth-promoting effects of SciTropin A™. Patients with ACTH deficiency should have their glucocorticoid replacement therapy carefully adjusted to avoid any inhibitory effect on growth.

Growth hormone decreases the conversion of cortisone to cortisol and may unmask previously undiscovered central hypoadrenalism or render low glucocorticoid replacement doses ineffective (see section 4.4).

In women on oral oestrogen replacement, a higher dose of growth hormone may be required to achieve the treatment goal (see section 4.4).

Data from an interaction study performed in growth hormone deficient adults suggests that somatropin administration may increase the clearance of compounds known to be metabolized by cytochrome P450 isoenzymes. The clearance of compounds metabolized by cytochrome P450 3A4 (e.g. sex steroids, corticosteroids, anticonvulsants and cyclosporin) may be especially increased resulting in lower plasma levels of these compounds. The clinical significance of this is unknown.

Also see section 4.4 for statements regarding diabetes mellitus and thyroid disorders and section 4.2 for statement on oral estrogen replacement therapy.

4.6 Fertility, pregnancy, and lactation

Pregnancy

There are no or limited amount of data from the use of somatropin in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). Somatropin is not recommended during pregnancy and in women of childbearing potential not using contraception.

Breast-feeding

There have been no clinical studies conducted with somatropin containing products in breast-feeding women. It is not known if somatropin is excreted into breast milk, but absorption of intact protein from the gastrointestinal tract of the infant is extremely unlikely. Therefore, caution should be exercised when is administered to breast-feeding women.

Fertility
Fertility studies with SciTropin A™ have not been performed.

4.7 Effects on ability to drive and use machines

SciTropin A™ has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile
Patients with growth hormone deficiency are characterised by extracellular volume deficit. When treatment with somatropin is started this deficit is rapidly corrected. Adverse reactions related to fluid retention, such as peripheral oedema and arthralgia are very common; musculoskeletal stiffness, myalgia and paraesthesia are common. In general, these adverse reactions are mild to moderate, arise within the first months of treatment and subside spontaneously or with dose-reduction.
The incidence of these adverse reactions is related to the administered dose, the age of patients, and possibly inversely related to the age of patients at the onset of growth hormone deficiency. SciTropin A™ has given rise to the formation of antibodies in approximately 1% of the patients. The binding capacity of these antibodies has been low and no clinical changes have been associated with their formation (see section 4.4).

Tabulated list of adverse reactions
Table 1 shows the adverse reactions ranked under headings of System Organ Class and frequency using the following convention: very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1000, <1/100); rare (≥1/10,000, <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data) for each of the indicated conditions.

Table 1

System organ Class	**Very common (≥1/10)**	**Common (≥1/100 to <1/10)**	**Uncommon (≥1/1,000 to <1/100)**	**Rare (≥1/10,000 to <1/1000)**	**Very rare (<1/10,000)**	**Not known (cannot be estimated from available data)**
Neoplasms benign, malignant, and unspecified (including cysts and polyps)			(Children) Leukaemia†			
Endocrine disorders						Hypothyroidism**
Metabolism and nutrition disorders						(Adults and Children) Type 2 diabetes mellitus
Nervous system disorders		(Adults) Paraesthesia* (Adults) Carpal tunnel syndrome	(Children) Benign intracranial hypertension (Children) Paraesthesia*			(Adults) Benign intracranial hypertension (Adults and Children) Headache
Skin and subcutaneous tissue disorders			(Children) Rash**, Pruritus**, Urticaria**			(Adults) Rash**, Pruritus**, Urticaria**
Musculoskeletal and connective tissue disorders	(Adults) Arthralgia*	(Adults) Myalgia* (Adults) Musculoskeletal stiffness* (Children) Arthralgia*	(Children) Myalgia*			(Children) Musculoskeletal stiffness*
Reproductive system and breast disorders			(Adults and Children) Gynaecomastia			
General disorders and administration site conditions	(Adults) Oedema peripheral*	(Children) Injection-site reaction$	(Children) Oedema peripheral*			(Adults and Children) Face oedema* (Adults) Injection-site reaction$
Investigations						(Adults and Children) Blood cortisol decreased‡

* In general, these adverse effects are mild to moderate, arise within the first months of treatment, and subside spontaneously or with dose-reduction. The incidence of these adverse effects is related to the administered dose, the age of the patients, and possibly inversely related to the age of the patients at the onset of growth hormone deficiency.

**Adverse drug reaction (ADR) identified post-marketing
$ Transient injection site reactions in children have been reported.
‡ Clinical significance is unknown
† Reported in growth hormone deficient children treated with somatropin, but the incidence appears to be similar to that in children without growth hormone deficiency.

Description of selected adverse reactions

Reduced serum cortisol levels

Somatropin has been reported to reduce serum cortisol levels, possibly by affecting carrier proteins or by increased hepatic clearance. The clinical relevance of these findings may be limited. Nevertheless, corticosteroid replacement therapy should be optimised before initiation of therapy.

Prader-Willi syndrome

In the post-marketing experience rare cases of sudden death have been reported in patients affected by Prader-Willi syndrome treated with somatropin.

Leukaemia

Cases of leukaemia (rare or very rare) have been reported in growth hormone deficient children treated with somatropin and included in the post-marketing experience. However, there is no evidence of an increased risk of leukaemia without predisposition factors, such as radiation to the brain or head.

Slipped capital femoral epiphysis and Legg-Calvé-Perthes disease

Slipped capital femoral epiphysis and Legg-Calvé-Perthes disease have been reported in children treated with GH. Slipped capital femoral epiphysis occurs more frequently in case of endocrine disorders and Legg-Calvé-Perthes is more frequent in case of short stature. But it is unknown if these 2 pathologies are more frequent or not while treated with somatropin. Their diagnosis should be considered in a child with a discomfort or pain in the hip or knee.

Other adverse drug reactions

Other adverse drug reactions may be considered somatropin class effects, such as possible hyperglycaemia caused by decreased insulin sensitivity, decreased free thyroxin level and benign intra-cranial hypertension.

Very rare occurrence of uneven or lumpy skin around the injection area if injection site does not vary.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

Pharmaceutical Industry Reporting Contacts

PT ETANA BIOTECHNOLOGIES INDONESIA
Kawasan Industri Pulogadung, Jl. Rawa Gelam V, Blok. L, Kav. 11-13, Jakarta
Email: pv@id.etanabiotech.com
Website: https://ebi-pharmacovigilance.azurewebsites.net/

MESO Center / National Pharmacovigilance Center

Badan Pengawas Obat dan Makanan Deputi Bidang Pengawasan Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif
Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif
Jl. Percetakan Negara 23 Jakarta Pusat, 10560
No Telp: (021) 4244691 ext. 1079
Email: pv-center@pom.go.id dan Indonesia-MESO-BadanPOM@hotmail.com
Website: https://e-meso.pom.go.id/ADR

4.9 Overdose

Symptoms:
Acute overdose could lead initially to hypoglycaemia and subsequently to hyperglycaemia.
Long-term overdose could result in signs and symptoms consistent with the known effects of human growth hormone excess.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics

Pharmacotherapeutic group: Anterior pituitary lobe hormones and analogues. ATC code: H01AC01.

Mechanism of action

Somatropin is a potent metabolic hormone of importance for the metabolism of lipids, carbohydrates and proteins. In children with inadequate endogenous growth hormone, somatropin stimulates linear growth and increases growth rate. In adults as well as in children, somatropin maintains a normal body composition by increasing nitrogen retention and stimulation of skeletal muscle growth, and by mobilization of body fat. Visceral adipose tissue is particularly responsive to somatropin. In addition to enhanced lipolysis, somatropin

decreases the uptake of triglycerides into body fat stores. Serum concentrations of IGF-I (Insulin-like Growth Factor-I) and IGFBP3 (Insulin-like Growth Factor Binding Protein 3) are increased by somatropin. In addition, the following actions have been demonstrated.

Pharmacodynamic effects

Lipid metabolism
Somatropin induces hepatic LDL cholesterol receptors, and affects the profile of serum lipids and lipoproteins. In general, administration of somatropin to growth hormone deficient patients results in reduction in serum LDL and apolipoprotein B. A reduction in serum total cholesterol may also be observed

Carbohydrate metabolism
Somatropin increases insulin but fasting blood glucose is commonly unchanged. Children with hypopituitarism may experience fasting hypoglycaemia. This condition is reversed by somatropin.

Water and mineral metabolism
Growth hormone deficiency is associated with decreased plasma and extracellular volumes. Both are rapidly increased after treatment with somatropin. Somatropin induces the retention of sodium, potassium and phosphorous.

Bone metabolism
Somatropin stimulates the turnover of skeletal bone. Long-term administration of somatropin to growth hormone deficient patients with osteopoenia results in an increase in bone mineral content and density at weight-bearing sites.

Physical capacity
Muscle strength and physical exercise capacity are improved after long-term treatment with somatropin. Somatropin also increases cardiac output, but the mechanism has yet to be clarified. A decrease in peripheral vascular resistance may contribute to this effect.

5.2 Pharmacokinetics properties

Absorption
The bioavailability of subcutaneously administered somatropin is approximately 80% in both healthy subjects and growth hormone deficient patients.
A subcutaneous dose of 5 mg of SciTropin A™ 5mg/1.5mL Solution for Injection in healthy adults results in plasma C_{max} and T_{max} values of 72±28 µg/L and 4.0±2.0 hours, respectively.
A subcutaneous dose of 5mg of SciTropin A™ 10mg/1.5mL Solution for Injection in healthy adults results in plasma C_{max} and T_{max} values of 74±22µg/L and 3.9±1.2 hours, respectively.

Elimination
The mean terminal half-life of somatropin after intravenous administration in growth hormone deficient adults is about 0.4 hours. However, after subcutaneous administration of SciTropin A™, a half- life of 3 hours is achieved. The observed difference is likely due to slow absorption from the injection site following subcutaneous administration.
Sub-populations
The absolute bioavailability of somatropin seems to be similar in males and females following subcutaneous administration.
Information about the pharmacokinetics of somatropin in geriatric and paediatric populations, in different races and in patients with renal, hepatic or cardiac insufficiency is either lacking or incomplete.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

SciTropin A™ Solution for Injection 5 mg/1.5 mL
disodium hydrogen phosphate heptahydrate, sodium dihydrogen phosphate dihydrate, mannitol, phosphoric acid, poloxamer 188, sodium hydroxide, benzyl alcohol, water for injections

SciTropin A™ Solution for Injection 10 mg/1.5 mL
disodium hydrogen phosphate heptahydrate, sodium dihydrogen phosphate dihydrate, glycine, phosphoric acid, poloxamer 188, sodium hydroxide, phenol, water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medical product must not be mixed with other medicinal products.

6.3 Shelf life after first use

After first use the cartridge should remain in the pen and has to be kept in a refrigerator (2°C - 8°C) for a maximum of 28 days. Store and transport refrigerated (2°C - 8°C). Do not freeze. Store in the original pen in order to protect from light.

6.4 Special precautions for storage

Unopened cartridge
Store and transport refrigerated (2°C - 8°C). Do not freeze. Store in the original package in order to protect from light.
For storage conditions of the in-use medicinal product, see section 6.3.

6.5 Nature and contents of container

1.5 mL of solution in a cartridge (colourless type I glass) with plunger on one side (siliconised bromobutyl), a disc (bromobutyl) and a cap (aluminium) on the other side. Pack sizes of 1 or 2. Not all presentations are marketed.

6.6 Special precautions for disposal and other handling

SciTropin A™ 5mg/1.5mL (15IU) Solution for Injection

SciTropin A™ 5 mg/1.5 mL solution for injection is a sterile, ready-to-use solution for subcutaneous injection filled in a glass cartridge.

This presentation is intended for multiple use. It should only be administered with a compatible injection pen device specifically developed for use with SciTropin A™ 5 mg/1.5 mL solution for injection. It has to be administered using sterile, disposable pen needles.

SciTropin A™ 10mg/1.5mL (30IU) Solution for Injection

SciTropin A™ 10 mg/1.5 mL solution for injection is a sterile, ready-to-use solution for subcutaneous injection filled in a glass cartridge.

This presentation is intended for multiple use. It should only be administered with a compatible injector pen device specifically developed for use with SciTropin A™ 10 mg/1.5 mL solution for injection. It has to be administered using sterile, disposable pen needles.

Patients and caregivers have to receive appropriate training and instruction on the proper use of the SciTropin A™ cartridges and the injector pen device from the physician or other suitable qualified health professionals.

The following is a general description of the administration process. The manufacturer's instructions with each pen must be followed for loading the cartridge, attaching the injection needle and for the administration.

1. Hands should be washed.
2. If the solution is cloudy or contains particulate matter, it should not be used. The content must be clear and colourless.
3. Disinfect the rubber membrane of the cartridge with a cleansing swab
4. Insert the cartridge into the injection pen device following the instructions for use provided with the pen.
5. Clean the site of injection with an alcohol swab.
6. Administer the appropriate dose by subcutaneous injection using a sterile pen needle. Remove the pen needle and dispose of it in accordance with local requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

Packaging

5 mg/1.5 mL (15 IU) Cartridge	No. Reg. DKI2280303243A1
10mg/1.5mL (30 IU) Cartridge	No. Reg. DKI2280303243B1

Box, 1 Cartridge @1.5 mL

Obat : jauhkan dari jangkauan anak-anak

HARUS DENGAN RESEP DOKTER

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi

Manufactured by:

Novartis Pharmaceutical Manufacturing GmbH
Langkampfen – Austria

Secondary Packager:

CEVA Logistics Solutions Singapore Pte. Ltd.

For SciGen Pte. Ltd.
Singapore

Imported by :

PT. Etana Biotechnologies Indonesia
Jakarta - Indonesia

Date of First Authorisation/Renewal of The Authorisation

Date of first authorisation: 29 November 2022

Date of Revision of The Text

Sep 2025

SciTropin A™

SciTropin A™ 5mg/1.5mL Larutan untuk Injeksi
SciTropin A™ 10mg/1.5mL Larutan untuk Injeksi

Bacalah semua leaflet ini dengan seksama sebelum Anda mulai menggunakan obat ini karena mengandung informasi penting untuk Anda.
- Simpan leaflet ini. Anda mungkin perlu membacanya lagi.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter, apoteker, atau perawat Anda.
- Obat ini hanya diresepkan untuk Anda. Jangan berikan itu kepada orang lain. Ini dapat membahayakan mereka, bahkan jika tanda-tanda penyakit mereka sama dengan Anda.
- Jika Anda mendapatkan efek samping, bicarakan dengan dokter, apoteker, atau perawat Anda. Hal ini termasuk kemungkinan efek samping yang tidak tercantum dalam leaflet ini. Lihat bagian 4.

Apa yang ada di leaflet ini:

1. Apa itu SciTropin A™ dan kegunaannya

SciTropin A™ adalah hormon pertumbuhan manusia rekombinan (juga disebut somatropin). Ini memiliki struktur yang sama dengan hormon pertumbuhan alami manusia yang dibutuhkan untuk tulang dan otot untuk tumbuh. Ini juga membantu jaringan lemak dan otot Anda berkembang dalam jumlah yang tepat. Ini adalah produk rekombinan yang artinya tidak terbuat dari jaringan manusia atau hewan.
SciTropin A™ digunakan untuk mengobati anak-anak yang tumbuh terlalu lambat karena kekurangan hormon pertumbuhan atau sindrom Turner, dan sebagai terapi pengganti pada orang dewasa dengan kekurangan hormon pertumbuhan yang nyata.
Namun, dokter Anda mungkin telah meresepkan SciTropin A™ untuk tujuan lain. Tanyakan kepada dokter Anda jika Anda memiliki pertanyaan tentang mengapa SciTropin A™ diresepkan untuk Anda
Anda hanya boleh diberikan obat ini oleh dokter yang berpengalaman dengan pengobatan hormon pertumbuhan dan yang telah mengkonfirmasi diagnosis Anda.

2. Apa yang perlu Anda ketahui sebelum menggunakan SciTropin A™

Jangan gunakan SciTropin A™ jika
- jika Anda alergi (hipersensitif) terhadap somatropin atau bahan lain dari SciTropin A™.
- jika Anda memiliki tumor aktif (kanker). Tumor harus tidak aktif dan Anda harus menyelesaikan pengobatan anti-tumor Anda sebelum memulai pengobatan dengan SciTropin A™.
- jika SciTropin A™ telah diresepkan untuk merangsang pertumbuhan tetapi Anda sudah berhenti tumbuh (epifisis tertutup).
- jika Anda sakit parah (misalnya, komplikasi setelah operasi jantung terbuka, operasi perut, trauma tak disengaja, gagal napas akut, atau kondisi serupa). Jika Anda akan menjalani, atau pernah menjalani, operasi besar, atau pergi ke rumah sakit karena alasan apa pun, beri tahu dokter Anda dan ingatkan dokter lain bahwa Anda menggunakan hormon pertumbuhan.

Peringatan dan pencegahan
Bicaralah dengan dokter Anda sebelum menggunakan SciTropin A™.
- Jika Anda menjalani terapi pengganti dengan glukokortikoid, Anda harus berkonsultasi dengan dokter secara teratur, karena Anda mungkin memerlukan penyesuaian dosis glukokortikoid Anda.
- Jika Anda berisiko terkena diabetes, dokter Anda perlu memantau kadar gula darah Anda selama terapi dengan somatropin.
- Jika Anda menderita diabetes, Anda harus memantau kadar gula darah Anda selama pengobatan dengan somatropin dan mendiskusikan hasilnya dengan dokter Anda untuk menentukan apakah Anda perlu mengubah dosis obat untuk mengobati diabetes.
- Setelah memulai pengobatan somatropin, beberapa pasien mungkin perlu memulai penggantian hormon tiroid.
- Jika Anda menerima pengobatan dengan hormon tiroid, mungkin perlu untuk menyesuaikan dosis hormon tiroid Anda.
- Jika Anda telah meningkatkan tekanan intrakranial (yang menyebabkan gejala, seperti sakit kepala yang parah, gangguan penglihatan atau muntah), Anda harus memberi tahu dokter Anda tentang hal itu.
- Jika Anda berjalan dengan pincang atau jika Anda mulai pincang selama perawatan hormon pertumbuhan, Anda harus memberi tahu dokter Anda.
- Jika Anda menerima somatropin untuk kekurangan hormon pertumbuhan setelah tumor sebelumnya (kanker), Anda harus diperiksa secara teratur untuk kekambuhan tumor atau kanker lainnya.
- Jika Anda mengalami sakit perut yang semakin parah, Anda harus memberi tahu dokter Anda.
- Pengalaman pada pasien di atas 80 tahun terbatas. Orang tua mungkin lebih sensitif terhadap aksi somatropin, dan karena itu mungkin lebih rentan untuk mengembangkan efek samping.
- SciTropin A™ dapat menyebabkan radang pankreas, yang menyebabkan nyeri hebat di perut dan punggung. Hubungi dokter Anda jika Anda atau anak Anda mengalami perut kembung setelah menggunakan SciTropin A™.
- Peningkatan kelengkungan tulang belakang ke samping (skoliosis) dapat terjadi pada setiap anak selama masa pertumbuhan yang cepat. Selama pengobatan dengan somatropin, dokter Anda akan memeriksa Anda (atau anak Anda) untuk mencari tanda-tanda skoliosis.

Obat-obatan lain dan SciTropin A™
Beri tahu dokter atau apoteker Anda jika Anda menggunakan, baru saja menggunakan atau mungkin menggunakan obat lain.
Secara khusus, beri tahu dokter Anda jika Anda sedang atau baru saja mengonsumsi obat- obatan berikut. Dokter Anda mungkin perlu menyesuaikan dosis SciTropin A™ atau obat lain:
- obat untuk mengobati kencing manis,
- hormon tiroid,
- obat-obatan untuk mengontrol epilepsi (antikonvulsan),
- ciclosporin (obat yang melemahkan sistem kekebalan setelah transplantasi),
- estrogen yang diambil secara oral atau hormon seks lainnya,
- hormon adrenal sintetis (kortikosteroid).

Dokter Anda mungkin perlu menyesuaikan dosis obat-obatan ini atau dosis somatropin.

Kehamilan dan menyusui
Anda tidak boleh menggunakan SciTropin A™ jika Anda sedang hamil atau menjalani program kehamilan. Mintalah saran dari dokter apoteker Anda jika Anda sedang hamil atau menyusui. Ini karena benzil alkohol dapat menumpuk di tubuh Anda dan dapat menyebabkan efek samping (disebut "asidosis metabolik").

Informasi penting tentang beberapa bahan SciTropin A™
SciTropin A™ 5mg / 1.5ml Larutan untuk Injeksi
Obat ini mengandung kurang dari 1 mmol natrium (23 mg) per ml, yaitu pada dasarnya 'bebas natrium'.
Obat ini mengandung 9mg, benzil alkohol dalam setiap ml. Benzil alkohol dapat menyebabkan reaksi alergi. Benzil alkohol telah dikaitkan dengan risiko efek samping yang parah termasuk masalah pernapasan (disebut "sindrom terengah-engah") pada anak kecil.
Jangan berikan kepada bayi Anda yang baru lahir (sampai dengan 4 minggu) karena mengandung benzil alkohol. Zat ini dapat menyebabkan reaksi toksik dan reaksi alergi pada bayi dan anak-anak hingga usia 3 tahun.

Jangan gunakan selama lebih dari seminggu pada anak kecil (kurang dari 3 tahun), kecuali disarankan oleh dokter atau apoteker Anda.

Mintalah saran dari dokter atau apoteker Anda jika Anda memiliki penyakit hati atau ginjal. Ini karena benzil alkohol dalam jumlah besar dapat menumpuk di tubuh Anda dan dapat menyebabkan efek samping (disebut "asidosis metabolik").

SciTropin A™ 10mg / 1.5ml Larutan untuk Injeksi
Obat ini mengandung kurang dari 1 mmol sodium (23 mg) per ml, yaitu dasarnya 'sodium- free'

3. Bagaimana Cara Penggunaan SciTropin A™

Selalu gunakan obat ini persis seperti yang dikatakan dokter atau apoteker atau perawat Anda. Tanyakan kepada dokter, perawat, atau apoteker Anda jika Anda tidak yakin.
Dosis tergantung pada ukuran Anda, kondisi yang Anda sedang dirawat dan seberapa baik hormon pertumbuhan bekerja untuk Anda. Setiap orang berbeda. Dokter Anda akan memberi tahu Anda tentang dosis SciTropin A™ individual Anda dalam miligram (mg) baik dari berat badan Anda dalam kilogram (kg) atau luas permukaan tubuh Anda yang dihitung dari tinggi dan berat badan Anda dalam meter persegi (m2), serta perawatan Anda Jadwal. Jangan mengubah dosis dan jadwal pengobatan tanpa berkonsultasi dengan dokter Anda.

Menyuntikkan SciTropin A™
Suntikkan hormon pertumbuhan Anda pada waktu yang bersamaan setiap hari. Waktu tidur adalah waktu yang baik karena mudah diingat. Itu juga wajar untuk memiliki tingkat yang lebih tinggi dari hormon pertumbuhan di malam hari.
SciTropin A™ ditujukan untuk penggunaan ganda. Ini hanya boleh diberikan dengan Pen yang direkomendasikan oleh dokter, perawat atau apoteker Anda.
SciTropin A™ ditujukan untuk penggunaan subkutan. Ini berarti disuntikkan melalui jarum suntik pendek ke dalam jaringan lemak tepat di bawah kulit Anda. Kebanyakan orang melakukan suntikan ke paha atau pantat mereka. Lakukan injeksi Anda di tempat yang telah ditunjukkan oleh dokter Anda. Jaringan lemak kulit bisa menyusut di tempat suntikan. Untuk menghindari hal ini, gunakan tempat yang sedikit berbeda untuk injeksi Anda setiap kali. Ini memberi kulit Anda dan area di bawah kulit Anda waktu untuk pulih dari satu suntikan sebelum mendapat suntikan lain di tempat yang sama.

Dokter Anda seharusnya sudah menunjukkan cara menggunakan SciTropin A™. Selalu menyuntikkan SciTropin A™ persis seperti yang dikatakan dokter Anda. Anda harus memeriksakan diri ke dokter atau apoteker jika Anda tidak yakin.

Cara menyuntikkan SciTropin A™
Petunjuk berikut menjelaskan cara menyuntikkan SciTropin A™ sendiri. Silakan baca instruksi dengan seksama dan ikuti langkah demi langkah. Dokter Anda akan menunjukkan cara menyuntikkan SciTropin A™. Jangan mencoba menyuntik kecuali Anda yakin memahami prosedur dan persyaratan penyuntikan.

SciTropin A™ diberikan sebagai suntikan di bawah kulit.
- Periksa larutan dengan hati-hati sebelum menyuntikkannya dan gunakan hanya jika jernih dan tidak berwarna.
- Ubah tempat suntikan untuk meminimalkan risiko lipoatrofi lokal (pengurangan lokal jaringan lemak di bawah kulit).

Persiapan
Kumpulkan barang-barang yang diperlukan sebelum Anda mulai:
- kartrid dengan larutan SciTropin A™ untuk injeksi.

- perangkat injeksi yang direkomendasikan oleh dokter, apoteker, atau perawat Anda (tidak disertakan dalam kemasan; lihat Petunjuk Penggunaan yang disertakan bersama perangkat).
- jarum pena untuk injeksi subkutan (tidak disertakan dalam kemasan).
- 2 penyeka pembersih (tidak disertakan dalam kemasan).

Cuci tangan Anda sebelum melanjutkan ke langkah selanjutnya.

Menyuntikkan SciTropin A™
- Dengan kapas pembersih, desinfeksi membran karet kartrid.
- Isinya harus jernih dan tidak berwarna.
- Masukkan kartrid ke dalam pena untuk injeksi. Ikuti Petunjuk Penggunaan injektor pena. Untuk mengatur pena dial dosis.
- Pilih tempat penyuntikan. Tempat terbaik untuk injeksi adalah jaringan dengan lapisan lemak antara kulit dan otot, seperti paha atau perut (kecuali pusar atau pinggang).
- Pastikan Anda menyuntikkan setidaknya 1 cm dari tempat suntikan terakhir Anda dan Anda mengubah tempat di mana Anda menyuntik, seperti yang telah diajarkan.
- Sebelum Anda melakukan suntikan, bersihkan kulit Anda dengan baik dengan kapas alkohol. Tunggu hingga area tersebut mengering.
- Masukkan jarum ke dalam kulit dengan cara yang telah diajarkan oleh dokter Anda.

Setelah disuntik
- Setelah injeksi, tekan tempat injeksi dengan perban kecil atau kasa steril selama beberapa detik. Jangan memijat tempat suntikan.
- Lepaskan jarum dari pena menggunakan tutup jarum luar, dan buang jarumnya. Ini akan menjaga larutan SciTropin A™ tetap steril dan mencegah kebocoran. Ini juga akan menghentikan udara kembali ke pena dan jarum menyumbat. Jangan berbagi jarum Anda. Jangan berbagi pena Anda.
- Tinggalkan kartrid di pena, pasang tutup pena, dan simpan di lemari es.
- Larutannya harus jernih setelah dikeluarkan dari lemari es. Jangan gunakan jika larutan keruh atau mengandung partikel.

Jika Anda menggunakan lebih banyak SciTropin A™ dari yang seharusnya
Jika Anda menyuntikkan lebih banyak dari yang seharusnya, hubungi dokter atau apoteker Anda sesegera mungkin. Kadar gula darah Anda bisa turun terlalu rendah dan kemudian naik terlalu tinggi. Anda mungkin merasa gemetar, berkeringat, mengantuk atau "bukan diri Anda sendiri", dan Anda mungkin pingsan.

Jika Anda lupa menggunakan SciTropin A™
Jangan gunakan dosis ganda untuk mengganti dosis yang terlupakan. Yang terbaik adalah menggunakan hormon pertumbuhan Anda secara teratur. Jika Anda lupa menggunakan dosis, lakukan injeksi berikutnya pada waktu yang biasa keesokan harinya. Catat setiap suntikan yang terlewat dan beri tahu dokter Anda pada pemeriksaan berikutnya.

Jika Anda berhenti menggunakan SciTropin A™
Mintalah saran dari dokter Anda sebelum Anda berhenti menggunakan SciTropin A™.
Jika Anda memiliki pertanyaan lebih lanjut tentang penggunaan obat ini, tanyakan kepada dokter atau apoteker atau perawat Anda.

4. Kemungkinan efek samping

Seperti semua obat-obatan, obat ini dapat menyebabkan efek samping, meskipun tidak semua orang mendapatkannya. Efek samping yang sangat umum dan umum pada orang dewasa dapat dimulai dalam bulan-bulan pertama pengobatan dan dapat berhenti secara spontan atau jika dosis Anda dikurangi.

Efek samping yang sangat umum (dapat mempengaruhi lebih dari 1 dari 10 orang) meliputi:
Pada orang dewasa
- Nyeri sendi
- Retensi air (yang terlihat sebagai jari bengkak atau pergelangan kaki bengkak, dalam waktu singkat pada awal pengobatan)

Efek samping yang umum (dapat mempengaruhi hingga 1 dari 10 orang) meliputi:
Pada anak-anak
- Kemerahan, gatal atau nyeri di tempat suntikan
- Nyeri sendi

Pada orang dewasa
- Mati rasa/kesemutan
- Kekakuan di lengan dan kaki, nyeri otot
- Nyeri atau sensasi terbakar di tangan atau ketiak (dikenal sebagai sindrom Carpal Tunnel)

Efek samping yang tidak umum (dapat mempengaruhi hingga 1 dari 100 orang) meliputi:
Pada anak-anak
- Leukemia (Hal ini telah dilaporkan pada sejumlah kecil pasien defisiensi hormon pertumbuhan, beberapa di antaranya telah diobati dengan somatropin. Namun, tidak ada bukti bahwa insiden leukemia meningkat pada penerima hormon pertumbuhan tanpa faktor predisposisi.)
- Peningkatan tekanan intrakranial (yang menyebabkan gejala, seperti sakit kepala yang kuat, gangguan penglihatan atau muntah)
- Mati rasa/kesemutan
- Gatal
- Muncul benjolan gatal di kulit
- Ruam
- Nyeri otot
- Pembesaran payudara
- Retensi air (yang terlihat sebagai jari bengkak atau pergelangan kaki bengkak, dalam waktu singkat pada awal pengobatan)

Pada orang dewasa
- Pembesaran payudara

Tidak diketahui (frekuensi tidak dapat diperkirakan dari data yang tersedia):
- Diabetes tipe 2
- Penurunan kadar hormon Kortisol dalam darah Anda
- Pembengkakan wajah
- Sakit kepala
- Hypothyroidism

Pada anak-anak
- Kekakuan di lengan dan kaki, nyeri otot

Pada orang dewasa
- Peningkatan tekanan intrakranial (yang menyebabkan gejala seperti sakit kepala yang kuat, gangguan penglihatan atau muntah)
- Kemerahan, gatal atau nyeri di tempat suntikan
- Ruam
- Gatal
- Muncul benjolan gatal di kulit

Pembentukan antibodi terhadap hormon pertumbuhan yang disuntikkan tetapi ini tampaknya tidak menghentikan kerja hormon pertumbuhan.
Kulit di sekitar area injeksi bisa menjadi tidak rata atau menggumpal, tetapi ini tidak boleh terjadi jika Anda menyuntik di tempat yang berbeda setiap kali.
Ada kasus kematian mendadak yang jarang terjadi pada pasien dengan sindrom Prader-Willi. Namun, tidak ada kaitan yang ditemukan antara kasus-kasus ini dan pengobatan dengan SciTropin

A™.
Epifisis femoralis modal yang tergelincir dan penyakit Legg-Calvé-Perthes dapat dipertimbangkan oleh dokter Anda jika ketidaknyamanan atau nyeri di pinggul atau lutut dialami saat dirawat dengan SciTropin A™.
Kemungkinan efek samping lain yang terkait dengan perawatan Anda dengan hormon pertumbuhan mungkin termasuk yang berikut:
Anda (atau anak Anda) mungkin mengalami gula darah tinggi atau penurunan kadar hormon tiroid. Ini dapat diuji oleh dokter Anda dan jika perlu dokter Anda akan meresepkan perawatan yang memadai.
Jarang, peradangan pankreas telah dilaporkan pada pasien yang diobati dengan hormon pertumbuhan.
Jika Anda mendapatkan efek samping, bicarakan dengan dokter, apoteker atau perawat. Ini termasuk kemungkinan efek samping yang tidak tercantum dalam leaflet ini. Dengan melaporkan efek samping Anda dapat membantu memberikan informasi lebih lanjut tentang keamanan obat ini.

Pelaporan efek samping
Jika Anda mendapatkan efek samping, berbicara dengan dokter Anda. Termasuk kemungkinan efek samping yang tidak tercantum dalam brosur ini. Dengan melaporkan efek samping, Anda dapat membantu memberikan informasi lebih lanjut tentang keamanan obat ini.
Anda juga dapat melaporkan efek samping secara langsung melalui:
Kontak Pelaporan Industri Farmasi
PT Etana Biotechnologies Indonesia
Kawasan Industri Pulogadung, Jl. Rawa Gelam V, Blok. L, Kav. 11-13, Jakarta
Email: pv@id.etanabiotech.com
Website: https://ebi-pharmacovigilance.azurewebsites.net/

Pusat Farmakovigilans/MESO Nasional
Badan Pengawas Obat dan Makanan Deputi Bidang Pengawasan Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif
Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif
Jl. Percetakan Negara 23 Jakarta Pusat, 10560
No Telp: (021) 4244691 ext. 1079
Email: pv-center@pom.go.id dan Indonesia-MESO-BadanPOM@hotmail.com
Website: https://e-meso.pom.go.id/ADR

5. Bagaimana Cara Penyimpanan SciTropin A™
Jauhkan dari pandangan dan jangkauan anak-anak.
Jangan gunakan obat ini setelah tanggal kadaluwarsa yang tertera pada label dan karton setelah EXP. Tanggal kedaluwarsa mengacu pada hari terakhir bulan itu.
• Simpan dan bawa dalam lemari pendingin (2°C–8°C).
• Jangan dibekukan.
• Simpan dalam kemasan aslinya untuk melindungi dari cahaya.
• Setelah injeksi pertama, kartrid harus tetap berada di pen injektor dan harus disimpan di lemari es (2°C–8°C) dan hanya digunakan maksimal 28 hari.
Jangan gunakan SciTropin A™ jika Anda melihat bahwa larutannya keruh.
Jangan membuang obat-obatan melalui air limbah atau limbah rumah tangga. Tanyakan apoteker Anda bagaimana membuang obat-obatan yang tidak lagi Anda gunakan. Langkah- langkah ini akan membantu melindungi lingkungan.

6. Isi paket dan informasi lainnya
Apa kandungan SciTropin A™ 5mg / 1.5mL Larutan untuk Injeksi
Zat aktif SciTropin A™ adalah somatropin.
Setiap ml larutan mengandung 3,3 mg somatropin (sesuai dengan 10 IU)
Satu kartrid mengandung 5,0 mg (sesuai dengan 15 IU) somatropin dalam 1,5 ml.

Bahan-bahan lainnya adalah:
• dinatrium hidrogen fosfat heptahidrat
• natrium dihidrogen fosfat dihidrat
• manitol
• asam fosfat
• poloxamer 188
• natrium hidroksida
• benzil alkohol
• air untuk injeksi

Apa kandungan SciTropin A™ 10mg/1.5mL Larutan untuk Injeksi
Zat aktif SciTropin A™ adalah somatropin.
Setiap ml larutan mengandung 6,7 mg somatropin (setara dengan 20 IU)
Satu kartrid mengandung 10,0 mg (sesuai dengan 30 IU) somatropin dalam 1,5 ml.

Bahan-bahan lainnya adalah:
• dinatrium hidrogen fosfat heptahidrat
• natrium dihidrogen fosfat dihidrat
• glisin
• asam fosfat
• poloxamer 188
• natrium hidroksida
• fenol
• air untuk injeksi

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi

Seperti apa SciTropin A™ dan isi paketnya
SciTropin A™ adalah larutan yang jernih dan tidak berwarna untuk injeksi. Ukuran paket 1.

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Untuk SciGen Pte. Ltd.
Singapura

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PT. Etana Biotechnologies Indonesia
Jakarta, Indonesia

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