



**Note:**  
 Batch Number and Exp.  
 Date will be printed to the cartridge

<p>Case ID : 04HI4GJE02 ( Light Green Label )          Size : (W) 33 mm x (H) 27 mm          Colour : 4C ( C:20M:05Y:70K:03 ) Process Colour          Finishing : NA          Artist : Teck Kin</p>	<p><b>CHECK CAREFULLY/核对后请签名</b>          This PlateProof is for your careful approval.          Please check thoroughly as the responsibility          for its accuracy rests with you. Our valued clients,          (以后如有错误, 本公司恕不负责)  <b>IMPORTANT: This is digital proof, not intended</b>          for actual print quality and colour proofing          重要提醒: 此为电脑打印之样证。</p>	<p><input checked="" type="checkbox"/> <b>PLEASE TICK &amp; SIGN UPON APPROVE</b>  <b>APPROVED BY / DATE</b></p>
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DISETUJUI PER: ERIGMD2024VR12400014

**SciTropin A™**  
**Somatropin**  
 10 mg / 1,5 mL (30 IU) Cartridge  
 Larutan untuk Injeksi



04H14GJA02

**SciTropin A™**  
**Somatropin**

Dus, 1 Cartridge @ 1,5 mL

**Cartridge**  
 10 mg / 1,5 mL (30 IU)



**SciTropin A™**  
**Somatropin**  
 10 mg / 1,5 mL (30 IU) Cartridge  
 Larutan untuk Injeksi

No-Reg :DK1226030243B1  
 HET :

**Untuk injeksi subkutan**  
**Larutan untuk injeksi**

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi.



**SciTropin A™**  
**Somatropin**  
 10 mg / 1,5 mL (30 IU) Cartridge  
 Solution for Injection

For single patient use only.  
**Manufactured by / Diproduksi oleh :**  
 Novartis Pharmaceutical Manufacturing GmbH  
 Langkampfen - Austria  
**Secondary Packager / Pengemasan Sekunder :**  
 Bollore Logistics Singapore Pte. Ltd.  
 For SciGen Pte. Ltd.  
 Singapore  
**Imported by / Diimpor oleh :**  
 PT. Etana Biotechnologies Indonesia  
 Jakarta - Indonesia

**HARUS DENGAN RESEP DOKTER**

**Each cartridge (1.5 mL) contains :**  
 Somatropin 10.0 mg (30.0 IU)  
 Sodium hydrogen phosphate heptahydrate 1.34 mg  
 Sodium dihydrogen phosphate dihydrate 1.56 mg  
 Poloxamer 188 3.00 mg  
 Phenol 4.50 mg  
 Glycine 27.75 mg  
 Potassium acid phosphate 27.75 mg  
 Sodium hydroxide 4.50 mg  
 Water for injection ad 1.5 mL

**Usage and Dosage, Adverse Reactions, Contraindication :**  
 ad 1.5 mL  
 Arturik Injeksi  
 q.s.  
 Asam fosfat  
 Glinin  
 Fenol  
 Poloxamer 188  
 Natrium dihidrogen fosfat dihidrat  
 Natrium hidrogen fosfat heptahidrat  
 Somatropin  
 10,0 mg (30,0 IU)

**Penyimpanan :**  
 Cartridge harus tetap berada di dalam pena dan harus disimpan pada suhu 2°-8°C. Jangan dibekukan.  
 Jangan gunakan cartridge setelah 28 hari dari injeksi pertama.

**See Package insert.**

**Storage :**  
 Store 2°-8°C. Do not freeze.  
 The cartridge should remain in the pen and has to be stored at 2°-8°C.

**Discharge cartridge 28 days after the first injection.**

**Box, 1 Cartridge @ 1,5 mL**

**SciTropin A™**  
**Somatropin**  
 10 mg / 1,5 mL (30 IU) Cartridge  
 Solution for Injection

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi.

**SciTropin A™**  
**Somatropin**  
 10 mg / 1,5 mL (30 IU) Cartridge  
 Solution for Injection

Batch No. :  
 Mfg. Date :  
 Exp. Date :

Case ID : 04H14GJA02 (Light Green Box)  
 Size : (W)55 x (H)86 x (D)25 mm  
 (W)184.4 x (H)172.3mm (Open)  
 Finishing : NA  
 Artist : Eve

Process Color 4C  
 Cyan : 20  
 Magenta : 05  
 Yellow : 70  
 Black : 03

**CHECK CAREFULLY/核对后请签名**  
 This Plate/Proof is for your internal approval.  
 Please check thoroughly as the responsibility for its content will be yours only.  
**ID.REG. ERE-0100007VR12400014**  
**IMPORTANT:** This is digital proof, not intended for actual print quality and colour proofing  
 重要声明：此为数码打样之文件，并非印刷与分色的真实品质。

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 APPROVED BY / DATE

Date Out: **31/01/2024**

# 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 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/m <sup>2</sup> body surface area dose per day	IU/m <sup>2</sup> 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 lipatrophy. 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

#### 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.

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

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

#### 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 induce a state of insulin resistance and in some patients, hyperglycaemia. Therefore patients should be observed for evidence of glucose intolerance. In rare cases the diagnostic criteria for diabetes mellitus type II may be fulfilled as a result of the somatropin therapy, but risk factors such as obesity (including obese PWS patients), family history, steroid treatment, or pre-existing impaired glucose tolerance have been present in most cases where this occurred. In patients with an already manifest diabetes mellitus, the anti-diabetic therapy might require adjustment when somatropin is instituted.

#### Thyroid function

Growth hormone increases the extrathyroidal conversion of T4 to T3 which may result in a reduction in serum T4 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.

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.

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.

### 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.

#### Paediatric population

##### Pancreatitis

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

##### 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.

### 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 undiagnosed 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 it 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. In adults patients adverse reactions related to fluid retention, such as peripheral oedema, face oedema, musculoskeletal stiffness, arthralgia, 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. In children such adverse reactions are uncommon. 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

Tables 1–3 show 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.

### Clinical trials in children with GHD

Table 1 Long-term treatment of children with growth disturbance due to insufficient secretion of growth hormone						
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 <1/1,000	Very Rare <1/10,000	Not Known (cannot be estimated from available data)
Neoplasms Benign, Malignant and Unspecified (including cysts and polyps)			Leukaemia <sup>†</sup>			
Metabolism and Nutrition Disorders						Type 2 diabetes mellitus
Nervous System Disorders						Paraesthesia*, Benign intracranial hypertension, Headache
Endocrine Disorders						Hypothyroidism
Skin and Subcutaneous Tissue Disorders			Rash**, Pruritus**, Urticaria***			
Musculoskeletal, Connective Tissue and Bone Disorders			Arthralgia*			Myalgia*, Musculoskeletal stiffness*
Reproductive system and breast disorders			Gynecomastia			
General Disorders and Administration Site Conditions	Injection site reactions <sup>§</sup>					Oedema peripheral*, Face oedema*
Investigations						Blood cortisol decreased <sup>‡</sup>

\* 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.

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**Clinical trials in children with Turner syndrome**

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 <1/1,000	Very Rare <1/10,000	Not Known (cannot be estimated from available data)
Neoplasms Benign, Malignant and Unspecified (including cysts and polyps)						Leukaemia†
Metabolism and Nutrition Disorders						Type 2 diabetes mellitus
Nervous System Disorders						Paraesthesia*, Benign intracranial hypertension, Headache
Endocrine Disorders						Hypothyroidism
Skin and Subcutaneous Tissue Disorders						Rash**, Pruritus**, Urticaria**
Musculoskeletal, Connective Tissue and Bone Disorders	Arthralgia*					Myalgia* Musculoskeletal stiffness*
Reproductive system and breast disorders			Gynecomastia			
General Disorders and Administration Site Conditions						Oedema peripheral*, Face oedema, Injection site reaction <sup>§</sup>
Investigations						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.

**Clinical trials in adults with GHD**

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 <1/1,000	Very Rare <1/10,000	Not Known (cannot be estimated from available data)
Metabolism and Nutrition Disorders						Type 2 diabetes mellitus
Nervous System Disorders		Paraesthesia*, Carpal Tunnel Syndrome				Benign intracranial hypertension, Headache
Endocrine Disorders						Hypothyroidism
Skin and Subcutaneous Tissue Disorders						Rash**, Pruritus**, Urticaria**
Musculoskeletal, Connective Tissue and Bone Disorders	Arthralgia*	Myalgia* Musculoskeletal stiffness*				
Reproductive system and breast disorders			Gynecomastia			
General Disorders and Administration Site Conditions	Oedema peripheral*					Face oedema*, Injection site reaction <sup>§</sup>
Investigations						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

**Post-marketing experience:**

Below presented adverse drug reactions have been reported in post-marketing studies, along with frequency estimation from the available data:

Reproductive system and breast disorders: Gynaecomastia (Frequency: uncommon)

**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.

**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-1 (Insulin-like Growth Factor-1) 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 phosphorus.

**Bone metabolism**

Somatropin stimulates the turnover of skeletal bone. Long-term administration of somatropin to growth hormone deficient patients with osteopenia 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<sub>max</sub> and T<sub>max</sub> 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<sub>max</sub> and T<sub>max</sub> 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.

- Hands should be washed.
- If the solution is cloudy or contains particulate matter, it should not be used. The content must be clear and colourless.
- Disinfect the rubber membrane of the cartridge with a cleansing swab
- Insert the cartridge into the injection pen device following the instructions for use provided with the pen.
- Clean the site of injection with an alcohol swab.
- 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 5mg-Reg : DK12280303243A1

10mg/1.5mL (30 IU) Cartridge 10mg-Reg : DK12280303243B1

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 :**

Bollere Logistics Singapore Pte. Ltd.  
For SciGen Pte. Ltd.  
Singapore

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Jakarta - Indonesia

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Date Out: **02/02/2024**

**DISETUJUI BPOM: 21 JUNI 2022**

# 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
2. Apa yang perlu Anda ketahui sebelum Anda menggunakan SciTropin A™
3. Bagaimana cara menggunakan SciTropin A™
4. Kemungkinan efek samping
5. Bagaimana cara menyimpan SciTropin A™
6. Isi paket dan lainnya informasi

**1. Apa itu SciTropin A™ dan kegunaannya**

SciTropin A™ adalah hormon pertumbuhan manusia rekombinan (juga disebut somatotropin). 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 hanya boleh diberikan oleh ahli okh 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 somatotropin 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 somatotropin.
- Jika Anda menderita diabetes, Anda harus memantau kadar gula darah Anda selama pengobatan dengan somatotropin dan mendiskusikan hasilnya dengan dokter Anda untuk menentukan apakah Anda perlu mengubah dosis obat untuk mengobati diabetes.
- Setelah memulai pengobatan somatotropin, 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 somatotropin 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 somatotropin, 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™.

**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 somatotropin.

**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 pemapasan (disebut "sindrom terengah-engah") pada anak kecil. Jangan berikan kepada bayi Anda yang baru lahir (sampai dengan 4 minggu), kecuali jika direkomendasikan oleh dokter 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"). Karena adanya benzil alkohol, obat ini tidak boleh diberikan kepada bayi prematur atau neonatus, karena 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.

**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 (m<sup>2</sup>), 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 hormon 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 bagaimana SciTropin A™ harus menyuntikkan SciTropin A™ persis seperti yang dikatakan dokter Anda. Anda harus memeriksa 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 lipotrofi lokal (pengurangan lokal jaringan lemak di bawah kulit).

**Persiapan**

Kumpulkan barang-barang yang diperlukan sebelum Anda mulai:

- kartrid dengan larutan SciTropin A™ untuk injeksi.



- perangkan 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 pasien 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.
- Lanutannya 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 dimulakan 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)

**Efek samping yang umum (dapat mempengaruhi hingga 1 dari 10 orang) meliputi:**

**Pada anak-anak**

- Kemerahan sementara, gatal atau nyeri di tempat suntikan
- Nyeri sendi
- Ruam
- Muncul benjolan gatal di kulit

**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:**

• Pembesaran payudara

**Pada anak-anak**

- Retensi air (yang terlihat sebagai jari bengkak atau pergelangan kaki bengkak, untuk waktu yang singkat pada awal pengobatan)
- Gatal

**Efek samping yang jarang (dapat mempengaruhi hingga 1 dari 1.000 pasien) meliputi:**

**Pada anak-anak**

- Mati rasa/kesemutan
- Leukemia (Hal ini telah dilaporkan pada sejumlah kecil pasien defisiensi hormon pertumbuhan, beberapa di antaranya telah diobati dengan somatotropin. 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)
- Nyeri otot

**Tidak diketahui (frekuensi tidak dapat diperkirakan dari data yang tersedia):**

- Diabetes tipe 2
- Penurunan kadar hormon Kortisol dalam darah Anda
- Pembengkakan wajah

**Pada anak-anak**

- Kekakuan di lengan dan kaki

**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 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. Beberapa di antaranya telah diobati dengan somatotropin. 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)

Nyeri otot

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Peningkatan tekanan intrakranial (yang menyebabkan gejala, seperti sakit kepala yang kuat, gangguan penglihatan atau muntah)

Nyeri otot

DAFTAR ISI

DAFTAR ISI

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.

**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 kadaluwarsa 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

HARUS DENGAN RESEP DOKTER

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.

5mg/1.5mL (15 IU) Cartridge      5mg-Reg : DK12280303243A1  
10mg/1.5mL (30 IU) Cartridge    10mg-Reg : DK12280303243B1

**Diproduksi oleh:**

Novartis Pharmaceutical Manufacturing GmbH  
Langkampfen – Austria

**Pengemas Sekunder:**

Bollore Logistics Singapore Pte Ltd. Untuk  
SciGen Pte. Ltd. Singapura

**Diimpor oleh:**

PT. Etana Biotechnologies Indonesia Jakarta, Indonesia

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Artist : CHIN LIANG

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Yellow : 0  
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