

Consumer Medicine Information (CMI) summary

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

1. Why am I using Omnitrope?

Omnitrope contains the active ingredient somatropin. Omnitrope is used to treat short stature caused by the lack of growth hormone, and reduced growth in girls with Turner syndrome and children with kidney disease to help them grow at a normal rate.

For more information, see Section [1. Why am I using Omnitrope?](#) in the full CMI.

2. What should I know before I use Omnitrope?

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

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

For more information, see Section [2. What should I know before I use Omnitrope?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Omnitrope and affect how it works.

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

4. How do I use Omnitrope?

- The dose of Omnitrope is different for each person. Your doctor will tell you what the right dose for you or your child is.
- Follow the instructions provided and use Omnitrope until your doctor tells you to stop.

More instructions can be found in Section [4. How do I use Omnitrope?](#) in the full CMI.

5. What should I know while using Omnitrope?

Things you should do	<ul style="list-style-type: none">• Call your doctor if you experience nausea, vomiting, headaches, problems with your vision, limping, pain in the hips and/or knees.• Remind any doctor, dentist or pharmacist you visit that you are using Omnitrope.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine without your doctor's permission and do not miss injections regularly.• Do not shake the Omnitrope syringe, shaking can damage the medicine.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Omnitrope affects you.
Looking after your medicine	<ul style="list-style-type: none">• Store Omnitrope in the refrigerator at 2-8°C. Do not freeze.

For more information, see Section [5. What should I know while using Omnitrope?](#) in the full CMI.

6. Are there any side effects?

Common side effects are reactions at the injection site, painful joints, muscle aches and pains, muscle stiffness and swelling of the arms or legs. Side effects such as severe or recurring headaches, problems with your vision, nausea or vomiting, extreme tiredness, change to thirst or appetite, increased need to pass urine, limping, discomfort or pain in the hip or knee, and curvature of the spine can be serious and you may need medical attention. These side effects are rare.

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

Omnitrope®

Active ingredient(s): somatropin (rbe), recombinant growth hormone, r-hGH

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. Why am I using Omnitrope?](#)
- [2. What should I know before I use Omnitrope?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Omnitrope?](#)
- [5. What should I know while using Omnitrope?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Omnitrope?

Omnitrope contains the active ingredient somatropin (recombinant human growth hormone, or biosynthetic human growth hormone). It is a man-made substance which is produced in a laboratory. Omnitrope is identical to the body's own growth hormone.

Omnitrope is used to treat:

- Short stature caused by the lack of growth hormone. Omnitrope promotes the growth of the long bones (for example, upper legs) in children with reduced height due to lower than normal levels of growth hormone.
- Reduced growth in girls with Turner syndrome. Turner syndrome is a genetic disorder found in females. The condition may cause short stature and ovaries to not fully develop.
- Children with kidney disease, to help them grow at a normal rate.

However, your doctor may prescribe Omnitrope for another purpose. Ask your doctor if you have any questions about why Omnitrope has been prescribed for you.

2. What should I know before I use Omnitrope?

Warnings

Do not use Omnitrope if:

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

Your doctor will not prescribe Omnitrope if you:

- are a child and have closed epiphyses (this means that your bones have finished growing)
- have an active tumour (cancer) or evidence of cancer growth
- are currently being treated for cancer
- have a serious injury or illness, or surgical procedures, requiring intensive care
- have Prader-Willi syndrome and are severely overweight or have marked difficulty breathing
- are under the age of 3 years.

Tell your doctor if you:

- have or have had other medical conditions (diabetes mellitus, cancer, a kidney transplant, thyroid disease, adrenocortical insufficiency (also known as ACTH deficiency))
- take medicines for any other condition.

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

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

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether Omnitrope passes into breast milk.

3. What if I am taking other medicines?

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

Some medicines may interfere with Omnitrope and affect how it works.

Tell your doctor if you are taking:

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

- ciclosporin e.g. for the treatment of severe skin disease (psoriasis), rheumatoid arthritis or after transplant surgery
- hormone therapy e.g. HRT for oestrogen deficiency, menopause or osteoporosis (bone thinning), testosterone for hormone deficiency in men, or other hormone therapy for contraception ("the Pill"), endometriosis or some cancers.

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

4. How do I use Omnitrope?

How much to use

- The dose of Omnitrope is different for each person. Your doctor will tell you what the right dose for you or your child is.
- **Ask your doctor or pharmacist if you are unsure of the correct dose for you.** They will tell you exactly how much to use.
- Follow the instructions provided and use Omnitrope until your doctor tells you to stop.

When to use Omnitrope

- Omnitrope should be used in the evening if possible. Normally, growth hormone is made by the body at night. Giving the injection at night helps to copy this process.

How to use Omnitrope

- **After taking Omnitrope out of the refrigerator allow glass cartridge to reach room temperature (about 30 mins) prior to injection.**
- **Change the site of injection every day.**
- **Inspect the product carefully before use.**
Only use the injection if the solution is clear. If the solution is cloudy or contains particles, the contents must not be injected.

Omnitrope 5 mg/1.5 mL, 10 mg/1.5 mL and 15 mg/1.5 mL Solution for Injection

Reconstitution is not required for Omnitrope Solution for Injection. This medicine is ready-to-use.

Put the glass cartridge containing the Omnitrope solution in the injector pen. Use

- **Sure Pal 5 for Omnitrope 5 mg/1.5 mL Solution for Injection for SurePal 5**
- **Sure Pal 10 for Omnitrope 10 mg/1.5 mL Solution for Injection for SurePal 10 and**
- **SurePal 15 for Omnitrope 15 mg/1.5 mL Solution for Injection for SurePal 15**

Follow the instructions that come with the pen.

Remove the needle from the injector pen after each injection. Return the injector pen with the cartridge to the refrigerator after each use.

If you are using Omnitrope 5 mg/1.5 mL for SurePal 5 discard the cartridge 28 days after injecting the first dose.

If you are using Omnitrope 10 mg/1.5 mL for SurePal 10 discard the cartridge 28 days after injecting the first dose.

If you are using Omnitrope 15 mg/1.5 mL discard the cartridge 28 days after injecting the first dose.

If you forget to use Omnitrope

Omnitrope should be used regularly at the same time each day. If you forget to use a dose, have your next injection at the usual time the next day.

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

Tell your doctor, nurse or pharmacist if you forget to use your Omnitrope.

If you use too much Omnitrope

If you think that you have used too much Omnitrope, you may need urgent medical attention.

You should immediately:

- phone the Australian Poisons Information Centre (**by calling 13 11 26**), or the New Zealand National Poisons Information Centre (**by calling 0800 POISONS or 0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

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

5. What should I know while using Omnitrope?

Things you should do

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

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

Tell your doctor if you:

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

Remind any doctor, dentist or pharmacist you visit that you are using Omnitrope.

Things you should not do

- Do not stop using this medicine without your doctor's permission

- Omnitrope should be used strictly according to the instructions you have been given. Do not change your dose unless your doctor has told you to
- Do not miss injections regularly. Missing injections can reduce effectiveness and you risk being taken off growth hormone altogether
- Do not freeze Omnitrope
- Do not give your Omnitrope to anyone else, even if they have the same condition as you. Also do not let anyone use your injector pen.

Things to be careful of

Follow the instructions for administration of Omnitrope carefully.

Not following the instructions might decrease the activity of your medicine or lead to a broken pen injector or cartridge.

Driving or using machines

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

Looking after your medicine

- Follow the instructions in the carton on how to take care of your medicine properly.
- Store Omnitrope in the refrigerator at 2-8°C. Do not freeze.
- Use an insulated container for transporting your medicine if you are travelling.

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

- in the bathroom or near a sink, or
- in the car or on window

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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

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

Do not use this medicine after the expiry date.

6. Are there any side effects?

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

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

Side effects

Side effects	What to do
<p>Administration site disorders:</p> <ul style="list-style-type: none"> • a reaction at or around the injection site such as bruising, itching, redness or swelling • pain or hardness around the injection site <p>General disorders:</p> <ul style="list-style-type: none"> • swelling of the arms or legs • swelling of the face <p>Metabolism and nutrition disorders:</p> <ul style="list-style-type: none"> • extreme tiredness or change to thirst or appetite • increased thirst and need to pass urine, particularly if overweight or if anyone in your family has diabetes <p>Musculoskeletal disorders:</p> <ul style="list-style-type: none"> • discomfort or pain in the hip or knee • limping • curvature of the spine • painful joints or muscle aches and pains • unusual muscle stiffness <p>Nervous system disorders:</p> <ul style="list-style-type: none"> • nausea, vomiting, severe or recurring headaches or problems with your vision • tingling or numbness in your fingers, hands or feet in adults, pain or burning sensation in the hands or underarms (known as Carpal Tunnel Syndrome) <p>Skin disorders:</p> <ul style="list-style-type: none"> • rash • itching (pruritis) alone or with a rash (urticaria) 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p> <p>You must tell your doctor immediately if any of these side effects become serious as you may require medical attention.</p>

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

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

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems or to Medsafe at <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

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

7. Product details

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

What Omnitrope contains

Active ingredient (main ingredient)	somatropin
Other ingredients (inactive ingredients)	5 mg/1.5 mL, 10 mg/ 1.5 mL and 15 mg/ 1.5 mL: <ul style="list-style-type: none">• monobasic sodium phosphate• dibasic sodium phosphate heptahydrate• poloxamer• phosphoric acid• sodium hydroxide• water for injection 5 mg/ 1.5 mL: <ul style="list-style-type: none">• mannitol• benzyl alcohol 10 mg/ 1.5 mL: <ul style="list-style-type: none">• benzyl alcohol• phenol• glycine 15 mg/ 1.5 mL: <ul style="list-style-type: none">• phenol• sodium chloride
Potential allergens	mannitol (5 mg/1.5 mL only)

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

What Omnitrope looks like

Omnitrope 5 mg/1.5 mL Solution for Injection for SurePal 5 - clear and colourless solution. Each pack contains 1, 5 or 10 colourless glass cartridges (AUST R 224622).

Omnitrope 10 mg/1.5 mL Solution for Injection for SurePal 10 - clear and colourless solution. Each pack contains 1, 5 or 10 colourless glass cartridges (AUST R 224623).

Omnitrope 15 mg/1.5 mL Solution for Injection for SurePal 15 - clear and colourless solution. Each pack contains 1, 5 or 10 colourless glass cartridges (AUST R 205625).

Not all pack sizes may be available.

Who distributes Omnitrope

Omnitrope is distributed in Australia by:

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

Omnitrope is distributed in New Zealand by:

Sandoz New Zealand Limited
12 Madden Street
Auckland 1010
New Zealand
Tel 0800 726 369

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