

Omnitrope®

Somatropin (rbe) (recombinant human growth hormone, r-hGH)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Omnitrope.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you or your child.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Omnitrope is used for

This medicine is used to treat:

- short stature in children due to growth hormone deficiency
- girls with growth disturbance associated with Turner syndrome
- growth disturbance in children with chronic renal insufficiency.

It contains the active ingredient somatropin. Somatropin is a biosynthetic human growth hormone which is a protein molecule occurring naturally in humans. Omnitrope is identical to the body's own growth hormone.

Ask your doctor if you have any questions about why this medicine has been prescribed for you or your child.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

Before you use Omnitrope

When you must not use it

Do not use this medicine if you have an allergy to:

- somatropin, the active ingredient
- any of the other ingredients listed at the end of this leaflet under Product description.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use this medicine if you have any of the following medical conditions:

- active tumours or evidence of tumour growth
- serious injury or illness, or surgical procedures, requiring intensive care
- closed epiphyses if you are a child (this means that the growth area of the bones is unable to grow anymore)
- are currently being treated for cancer

- have Prader-Willi syndrome and are severely overweight or have marked difficulty breathing
- Do not give this medicine to a child under the age of 3 years.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you or your child should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- diabetes mellitus
- thyroid disease
- cancer
- any disorder relating to hormones including adrenocortical insufficiency (also known as ACTH deficiency)
- kidney transplant.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start using Omnitrope.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other

medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

In particular, tell your doctor if you are taking:

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

These medicines may be affected by Omnitrope or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use Omnitrope

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

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 they give you.

If you use the wrong dose, Omnitrope may not work as well and your problem may not improve.

How to use it

After taking Omnitrope out of the refrigerator allow glass cartridge to reach room temperature (about 30 mins) prior to injection.

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.

When to use Omnitrope

Omnitrope is usually injected once a day in the evening.

How long to use Omnitrope

Continue using your medicine for as long as your doctor tells you.

Your doctor will determine when your treatment should be stopped.

If you forget to use it

Inject your dose as soon as you remember, and continue to inject it as you would normally.

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

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much Omnitrope. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Omnitrope

Things you must do

If you are about to be started on any new medicine, remind your

doctor and pharmacist that you are using Omnitrope.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you become pregnant while using this medicine, tell your doctor immediately.

Tell your doctor if you start to have difficulty breathing or start to snore, or have an increase in snoring while you are using Omnitrope.

Tell your doctor if you stop or change your oral oestrogen therapy.

Tell your doctor if you stop or change your glucocorticoid therapy.

Keep all of your doctor's appointments so that your progress can be checked.

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.

Things you must not do

Do not use Omnitrope to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you. Also do not let anyone use your injector pen.

Do not stop using your medicine or change the dosage without checking with your doctor.

Things to be careful of

Because growth hormone may interfere with your body's use of insulin, you will have to be watchful of glucose intolerance during therapy.

Symptoms of glucose intolerance include increased thirst and need to pass urine.

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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Omnitrope.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- reactions at the injection site, such as bruising, pain, numbness, redness or swelling
- swelling of arms or legs
- joint and/or muscle pain
- stiffness of the hands and feet
- tingling or numbness in your fingers, hands or feet.

These are mild side effects of the medicine that usually only occur at the beginning of therapy but are also dependent on dose.

Tell your doctor as soon as possible if you notice any of the following:

- recurrent headache, blurred vision, nausea and/or vomiting
- swelling of the face
- increased thirst and need to pass urine, particularly if you are overweight or if anyone in your family has diabetes

- extreme tiredness, lethargy, muscle weakness or change to appetite
- curvature of the spine
- limping or pain in the hip and knee.

The above list includes serious side effects. You or your child may need urgent medical attention or hospitalisation. Serious side effects are rare.

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

Other side effects not listed above may also occur in some people.

After using Omnitrope

Storage

Keep your medicine in the original container. If you take it out of its original container it may not keep well.

Keep your medicine in the refrigerator at 2-8°C. Do not freeze.

Keep it where children cannot reach it.

Use an insulated container for transporting your medicine if you are travelling.

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

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.

Disposal

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 your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Omnitrope Solution for Injection is a clear and colourless solution.

Package quantities

Omnitrope 5 mg/1.5 mL, 10 mg/1.5 mL & 15 mg/1.5 mL Solution for Injection - Each pack contains 1, 5 or 10 colourless glass cartridges.

Ingredients

Active ingredients:

- Omnitrope 5 mg/1.5 mL for SurePal 5 - 3.33 mg/mL somatropin (rbe)
- Omnitrope 10 mg/1.5 mL for SurePal 10 - 6.67 mg/mL somatropin (rbe)
- Omnitrope 15 mg/1.5 mL for SurePal 15 - 10 mg/mL somatropin (rbe)

Inactive ingredients:

Omnitrope 5 mg/1.5 mL for SurePal 5:

- monobasic sodium phosphate
- dibasic sodium phosphate heptahydrate
- poloxamer
- mannitol
- benzyl alcohol
- phosphoric acid
- sodium hydroxide

- water for injection.

Omnitrope 10 mg/1.5 mL for Sure Pal 10:

- monobasic sodium phosphate
- dibasic sodium phosphate heptahydrate
- poloxamer
- phenol
- glycine
- phosphoric acid
- sodium hydroxide
- water for injections.

Solvent - Water for Injections:

- water for injections.

Solvent - Benzyl alcohol 1.5%:

- benzyl alcohol
- water for injections.

Omnitrope 15 mg/1.5 mL for Sure Pal 15:

- monobasic sodium phosphate
- dibasic sodium phosphate heptahydrate
- poloxamer
- phenol
- sodium chloride
- phosphoric acid
- sodium hydroxide
- water for injections

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

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Australia
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Omnitrope 5 mg/1.5 mL Solution for Injection for SurePal 5- AUST R 224622

Omnitrope 10 mg/1.5 mL Solution for Injection for SurePal 10 - AUST R 224623

Omnitrope 15 mg/1.5 mL Solution for Injection for SurePal 15 - AUST R 205625