

Omnitrope®  
solution for injection in cartridge

**Omnitrope®**  
solution for injection in cartridge

#### PACKAGE LEAFLET: INFORMATION FOR THE USER

**Omnitrope® 5 mg/1.5 ml solution for injection in cartridge**  
**Omnitrope® 10 mg/1.5 ml solution for injection in cartridge**  
**Omnitrope® 15 mg/1.5 ml solution for injection in cartridge**

#### somatropin

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

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

#### What is in this leaflet:

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

## 1 What Omnitrope is and what it is used for

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

#### In children Omnitrope is used to treat the following growth disturbances:

- If you are not growing properly and you do not have enough of your own growth hormone.
- If you have Turner syndrome. Turner syndrome is a chromosomal error in girls that can affect growth – your doctor will have told you if you have this.
- If you have chronic renal (kidney) insufficiency. As kidneys lose their ability to function normally, this can affect growth.
- If you were small or too light at birth. Growth hormone can help you grow taller if you have not been able to catch up or maintain normal growth by four years of age or later.
- If you have Prader-Willi syndrome (a chromosomal disorder). Growth hormone will help you grow taller if you are still growing, and will also improve your body composition. Your excessive fat will decrease and your reduced muscle mass will improve.

#### In adults Omnitrope is used to

- treat persons with pronounced growth hormone deficiency. This can start

during adult life or it can continue from childhood.

If you have been treated with Omnitrope for growth hormone deficiency during childhood, your growth hormone status will be retested after completion of growth. If severe growth hormone deficiency is confirmed, your doctor will propose continuation of Omnitrope treatment.

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

## 2 What you need to know before you use Omnitrope

#### Do not use Omnitrope and tell your doctor if

- You are allergic (hypersensitive) to somatropin or to any of the other ingredients of Omnitrope.
- You have an active tumour (cancer). Tumours must be inactive and you must have finished your anti-tumour treatment before you start your treatment with Omnitrope.
- You are seriously ill (for example, complications following open heart surgery, abdominal surgery, accidental trauma, acute respiratory failure, or similar conditions). If you are about to have, or have had, a major operation, or go into hospital for any reason, tell your doctor and remind the other doctors you are seeing that you use growth hormone.

- Omnitrope has been prescribed to stimulate growth but you have already stopped growing (closed epiphyses).

#### Warnings and precautions

#### Take special care with Omnitrope and tell your doctor if any of the following statements apply to you

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

#### Children with chronic renal (kidney) insufficiency:

- Your doctor should examine your kidney function and your growth rate before starting somatropin. Medical treatment for your kidney condition should be continued. Somatropin treatment should be stopped at kidney transplantation.

#### Children with Prader-Willi syndrome:

- Your doctor will give you diet restrictions to follow to control your weight.
- Your doctor will assess you for signs of upper airway obstruction, sleep apnoea (where your breathing is interrupted during sleep), or respiratory infection before you start treatment with somatropin.
- During treatment with somatropin, tell your doctor if you show signs of upper airway obstruction (including starting to snore or worsening of snoring), your doctor will need to examine you and may interrupt treatment with somatropin.
- During treatment, your doctor will check you for signs of scoliosis, a type of spinal deformity.
- During treatment, if you develop a lung infection, tell your doctor so that he can treat the infection.

#### Children born small or too light at birth:

- If you were too small or too light at birth and are aged between 9 and 12 years, ask your doctor for specific advice relating to puberty and treatment with this medicine.
- Treatment should be continued until you have stopped growing.
- Your doctor will check your blood sugar and insulin levels before the start of treatment and every year during treatment.

#### Other medicines and Omnitrope

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

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

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

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

#### Pregnancy and breast-feeding

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

Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. This is because benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

#### Important information about some of the ingredients of Omnitrope

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

Omnitrope 5 mg/1.5 ml solution for injection: This medicine contains 9 mg benzyl alcohol in each ml.

Benzyl alcohol may cause allergic reactions.

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

Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor.

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

Because of the presence of benzyl alcohol the medicinal product must not be given to premature babies or neonates. It may cause toxic reactions and allergic reactions in infants and children up to 3 years old.

Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.

## 3 How to use Omnitrope

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

#### Recommended dosage

The dose depends on your size, the condition for which you are being treated and how well growth hormone works for you. Everyone is different. Your doctor will advise you about your individualised dose of Omnitrope in milligrams (mg) from either your body weight in kilograms (kg) or your body surface area calculated from your height and weight in square metres (m<sup>2</sup>), as well as your treatment schedule. Do not change the dosage and treatment schedule without consulting your doctor.

#### The recommended dose is for:

**Children with growth hormone deficiency:** 0.025–0.035 mg/kg body weight per day or 0.7–1.0 mg/m<sup>2</sup> body surface area per day. Higher doses can be used. When growth hormone deficiency continues into adolescence, Omnitrope should be continued until completion of physical development.

**Children with Turner syndrome:** 0.045–0.050 mg/kg body weight per day or 1.4 mg/m<sup>2</sup> body surface area per day.

**Children with chronic renal (kidney) insufficiency:** 0.045–0.050 mg/kg body weight per day or 1.4 mg/m<sup>2</sup> body surface area per day. Higher doses may be necessary if the rate of growth is too low. Dosage adjustment may be necessary after 6 months of treatment.

**Children with Prader-Willi syndrome:** 0.035 mg/kg body weight per day or 1.0 mg/m<sup>2</sup> body surface area per day. The daily dosage should not exceed 2.7 mg. Treatment should not be used in children who have almost stopped growing after puberty.

#### Children born smaller or lighter than expected and with growth disturbance:

0.035 mg/kg body weight per day or 1.0 mg/m<sup>2</sup> body surface area per day. It is important to continue treatment until final height is reached. Treatment should be discontinued after the first year if you are not responding or if you have reached your final height and stopped growing.

#### Adults with growth hormone deficiency:

If you continue Omnitrope after treatment during childhood you should start with 0.2–0.5 mg per day. This dosage should be gradually increased or decreased according to blood test results as well as clinical response and side effects.

If your growth hormone deficiency starts during adult life you should start with 0.15–0.3 mg per day. This dosage should be gradually increased according to blood test results as well as clinical response and side effects. The daily maintenance dose seldom exceeds 1.0 mg per day. Women may require higher doses than men. Dosage should be monitored every 6 months. Persons above 60 years should start with a dose of 0.1–0.2 mg per day which should be slowly increased according to individual requirements. The minimum effective dose should be used. The maintenance dose seldom exceeds 0.5 mg per day. Follow the instructions given to you by your doctor.

#### Injecting Omnitrope

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

Omnitrope 5 mg/1.5 ml in a cartridge for SurePal 5 is intended for multiple use. It should only be administered with SurePal 5, an injection device specifically developed for use with Omnitrope 5 mg/1.5 ml solution for injection.

Omnitrope 10 mg/1.5 ml in a cartridge for SurePal 10 is intended for multiple use. It should only be administered with SurePal 10, an injection device specifically developed for use with Omnitrope 10 mg/1.5 ml solution for injection.

Omnitrope 15 mg/1.5 ml in a cartridge for SurePal 15 is intended for multiple use. It should only be administered with SurePal 15, an injection device specifically developed for use with Omnitrope 15 mg/1.5 ml solution for injection.

Omnitrope is intended for subcutaneous use. This means that it is injected through a short injection needle into the fatty tissue just under your skin. Most people do their injections into their thigh or their bottom. Do your injection in the place you have been shown by your doctor. Fatty tissue of the skin can shrink at the site of injection. To avoid this, use a different place for your injection each time. This gives your skin and the area under your skin time to recover from one injection before it gets another one in the same place.

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

#### How to inject Omnitrope

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

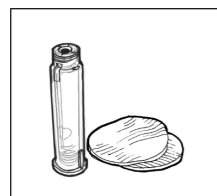
- Omnitrope is given as an injection under the skin.
- Carefully inspect the solution before injecting it and use only if clear and colourless.
- Change the injection sites to minimise the risk of local lipoatrophy (local reduction of fatty tissue under the skin).

*Continued on the next page >>*

## Preparation

Collect necessary items before you begin:

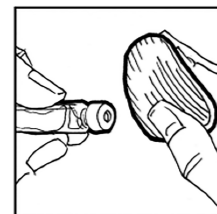
- a cartridge with Omnitrope solution for injection.



- SurePal, an injection device specifically developed for use with Omnitrope solution for injection (not supplied in the pack; see Instructions for Use provided with SurePal).
- a pen needle for subcutaneous injection (not supplied in the pack).
- 2 cleansing swabs (not supplied in the pack).

Wash your hands before you continue with the next steps.

## Injecting Omnitrope



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



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

## After injecting

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

## If you use more Omnitrope than you should

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

## If you forget to use Omnitrope

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

## If you stop using Omnitrope

Ask for advice from your doctor before you stop using Omnitrope.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

## 4 Possible side effects

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

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

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

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

- Joint pain
- Temporary reddening, itchiness or pain at the injection site

### In adults

- Pain or burning sensation in the hands or underarms (known as Carpal Tunnel syndrome)
- Numbness / tingling
- Stiffness in the arms and legs, muscle pain

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

#### In children

- Leukaemia (This has been reported in a small number of growth hormone deficiency patients, some of whom have been treated with somatropin. However, there is no evidence that leukaemia incidence is increased in growth hormone recipients without predisposing factors.)
- Increased intracranial pressure (which causes symptoms, such as strong headache, visual disturbances or vomiting)
- Numbness/tingling.
- Rash.
- Itching.
- Raised itchy bumps on the skin.
- Muscle pain.
- Breast enlargement (gynaecomastia).
- Water retention (which shows as puffy fingers or swollen ankles, for a short time at the start of treatment).

#### In adults

- Breast enlargement (gynaecomastia).

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

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

#### In children:

- Stiffness in the arms and legs.

#### In adults

- Increased intracranial pressure (which causes symptoms such as strong headache, visual disturbances or vomiting).
- Rash.
- Itching
- Raised itchy bumps on the skin.
- Reddening, itchiness or pain at the injection site.

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

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

There have been rare cases of sudden death in patients with Prader-Willi syndrome. However, no link has been made between these cases and treatment with Omnitrope.

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

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

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

## Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5 How to store Omnitrope

Keep out of the sight and reach of children.

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

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

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

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

## 6 Contents of the pack and other information

### What Omnitrope 5 mg/1.5 ml contains

- The active substance of Omnitrope is somatropin. Each ml of solution contains 3.3 mg of somatropin (corresponding to 10 IU) One cartridge contains 5.0 mg (corresponding to 15 IU) of somatropin in 1.5 ml.
- The other ingredients are: disodium hydrogen phosphate heptahydrate sodium dihydrogen phosphate dihydrate mannitol poloxamer 188 benzyl alcohol water for injections

### What Omnitrope 10 mg/1.5 ml contains

- The active substance of Omnitrope is somatropin. Each ml of solution contains 6.7 mg of somatropin (corresponding to 20 IU) One cartridge contains 10.0 mg (corresponding to 30 IU) of somatropin in 1.5 ml.
- The other ingredients are: disodium hydrogen phosphate heptahydrate sodium dihydrogen phosphate dihydrate glycine poloxamer 188 phenol water for injections

### What Omnitrope 15 mg/1.5 ml contains

- The active substance of Omnitrope is somatropin. Each ml of solution contains 10 mg of somatropin (corresponding to 30 IU). One cartridge contains 15.0 mg (corresponding to 45 IU) of somatropin in 1.5 ml.
- The other ingredients are: disodium hydrogen phosphate heptahydrate sodium dihydrogen phosphate dihydrate sodium chloride poloxamer 188 phenol water for injections

## What Omnitrope looks like and contents of the pack

Omnitrope is a clear and colourless solution for injection.

Omnitrope 5 mg/1.5 ml solution for injection is for use in SurePal 5 only.

Omnitrope 10 mg/1.5 ml solution for injection is for use in SurePal 10 only.

Omnitrope 15 mg/1.5 ml solution for injection is for use in SurePal 15 only.

Pack sizes of 1, 5 or 10.

Not all pack sizes may be marketed.

## Marketing Authorisation Holder

Sandoz GmbH  
Biochemiestr. 10  
A-6250 Kundl  
Austria

## Manufacturer

Sandoz GmbH  
Biochemiestrasse 10  
6336 Langkampfen  
Austria

## Or

Novartis Pharmaceutical Manufacturing GmbH  
Biochemiestrasse 10  
6336 Langkampfen  
Austria

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