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PACKAGE LEAFLET: INFORMATION FOR THE USER

Omnitrope® 3.3 mg/ml

solution for injection

Somatropin

SANDOZ

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT OMNITROPE IS AND WHAT IT IS USED FOR

Omnitrope is a human growth hormone which is made by a method known as 'recombinant DNA technology' using the bacterial microorganism E. coli. The structure is identical to the human body's own growth hormone.

Omnitrope is used for

- Treatment of infants, children, and adolescents:
  - with growth disturbance due to insufficient secretion of growth hormone (GH).
  - with growth disturbance associated with Turner syndrome.
  - with growth disturbance associated with chronic renal insufficiency (CRI).
  - with growth disturbance in short children/adolescents born small for gestational age (SGA), who failed to show catch-up growth by 4 years of age or later.
  - with Prader-Willi syndrome (PWS), for improvement of growth and body composition. The diagnosis of PWS should be confirmed by appropriate genetic testing.
- Replacement of growth hormone in adults with confirmed pronounced growth hormone deficiency (GHD) originating in either childhood or adulthood.

2. BEFORE YOU USE OMNITROPE

Diagnosis and therapy with Omnitrope should be initiated and monitored by doctors who are appropriately qualified and experienced in the diagnosis and management of patients with growth disorders.

Do not use Omnitrope

- If you are allergic (hypersensitive) to somatropin or to any of the other ingredients of Omnitrope.
- If there is any evidence of an active tumour. Anti-tumour therapy must be completed before starting therapy.
- To stimulate growth if growing is already finished (closed epiphyses).
- During acute life-threatening illness due to complications following open-heart surgery, abdominal surgery, multiple trauma caused by an accident, acute respiratory failure, or similar conditions.

Take special care with Omnitrope

- Somatropin may interfere with your body's use of insulin. Your blood glucose values will have to be checked regularly during therapy with somatropin.
- If you have diabetes mellitus or a family history of diabetes mellitus. Insulin therapy may need to be adjusted or started after somatropin therapy is initiated.
- Hypothyroidism (decrease in thyroid gland function) may develop during therapy with somatropin. Hypothyroidism may reduce the optimal response to somatropin. Therefore, thyroid hormone levels must be checked periodically during therapy.
- Benign intracranial hypertension (high pressure within the brain) has been reported during treatment with somatropin. If symptoms, such as recurrent headache, visual problems, nausea, or vomiting occur, please ask your doctor for advice. Your doctor may decide to perform an examination of the eyes to detect increased brain pressure. Depending on the results of this test, treatment with Omnitrope may have to be interrupted.
- Patients with endocrine (hormonal) disorders are more likely to have problems with their hips. If you develop a limp or pain in the hip, please ask your doctor for advice.
- Progression of scoliosis (a spine curved sideways) can occur in patients who experience rapid growth. Therefore, signs of scoliosis should be monitored during treatment with somatropin. However, somatropin treatment has not been shown to increase the frequency of occurrence or the severity of scoliosis.
- If you have had a previous malignant disease. You will have to be examined regularly for recurrence of the malignancy.
- There is no information available on the safety of growth hormone substitution therapy in patients with acute critical illness. If acute critical illness occurs, your doctor will have to carefully evaluate the safety of continuing somatropin treatment.
- Experience in patients above 60 years of age is limited.

Patients with chronic renal insufficiency (CRI)

- In patients with CRI, somatropin therapy should not be started unless the function of the kidney is below 50 percent of normal. To verify growth disturbance, growth should be followed for one year before starting therapy. Conservative treatment for CRI should be continued during treatment with somatropin. After kidney transplantation, treatment with somatropin should be stopped.

Patients with Prader-Willi syndrome (PWS)

- In patients with PWS, treatment with somatropin should always be combined with a calorie-restricted diet.
- Experience with prolonged treatment in patients with PWS is limited.
- There have been reports of deaths associated with the use of growth hormone in patients with PWS who had one or more of the following risk factors: severe obesity, history of severe breathing problems, especially during sleep, or infection of the lungs or airways. Patients with PWS and one or more of these risk factors may be at greater risk. Before starting on Omnitrope, you should be checked for breathing problems and respiratory infections by a doctor, even if you have not been experiencing any symptoms of breathing difficulty.
- If any infection of your lungs or airways is found, you must be treated sufficiently before starting treatment with somatropin. You should be monitored for signs of infection while being treated with somatropin.
- Difficulty breathing while asleep, called sleep apnoea, should be examined by a specialist. Before initiation of growth hormone therapy, you should be observed for breathing problems during the night using a special monitor. If any problems are found, then you should continue to be monitored during sleep.
- If during treatment with somatropin you show signs of breathing problems (onset or increase of snoring), treatment should be interrupted and the cause should be examined by a doctor.

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- All patients with PWS should have effective weight control before and during treatment with somatropin.

Patients born SGA
- In patients born SGA, other medical reasons or treatments that could explain the growth disturbance should be ruled out.
- Experience in starting treatment in SGA patients near the onset of puberty is limited. Therefore, treatment should not be started near the onset of puberty.
- Experience in patients with Silver-Russell syndrome is limited.
- Some of the height gain obtained with treating short children/adolescents born SGA with somatropin may be lost if treatment is stopped before final height is reached.
- Blood sugar and insulin levels should be checked before the start of treatment and annually during treatment with growth hormone.

Using other medicines
- Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

It is especially important to tell your doctor if you are taking any medicine for diabetes, thyroid disorder or any anticonvulsants, ciclosporin or steroid hormones such as oestrogens, progesterone or corticosteroids. A dose adjustment may be needed for these medicines.

Pregnancy and breast-feeding
Treatment with Omnitrope should be interrupted during pregnancy.
Ask your doctor for advice before using Omnitrope if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

No studies of the effects on the ability to drive and use machines have been performed.

Important information about some of the ingredients of Omnitrope
This medicinal product contains less than 1 mmol sodium (23 mg) per ml, i.e. essentially 'sodium- free'.

One ml contains 9 mg benzyl alcohol.

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

3. HOW TO USE OMNITROPE

Omnitrope 3.3 mg/ml is intended for multiple use. It should only be administered with the Omnitrope Pen 5, an injection device specifically developed for use with Omnitrope 3.3 mg/ml solution for injection.

Omnitrope is given through a short injection needle into the fatty tissue just under your skin. You will receive appropriate training and instruction on the proper use of Omnitrope from your doctor or other suitably qualified health professional. For instructions on how to inject Omnitrope, see section "How to inject Omnitrope" below.

Treatment with somatropin is a long-term treatment. If you want to know more about what that means for you, please ask your doctor.

How much and how often to use Omnitrope
Your doctor will advise you about your individualised dose of Omnitrope and treatment schedule. Usually Omnitrope is injected once a day in the evening. Please do not change the dosage and treatment schedule without consulting your doctor.

Dose adjustments may be required over time, depending on your increase in body weight and response.

If you use more Omnitrope than you should
Acute overdose may lead initially to hypoglycaemia (decrease in blood glucose) and subsequently to hyperglycaemia (increase in blood glucose). Long-term overdosage could result in signs and symptoms of gigantism or acromegaly (enhanced growth of ears, nose, lips, tongue, and cheekbones). If you have used more Omnitrope than you should, please ask your doctor for advice.

If you forget to take Omnitrope
Do not inject a double dose to make up for forgotten individual doses. Continue with the prescribed dosage regimen. If you forget to take Omnitrope, please ask your doctor for advice.

How to inject Omnitrope 3.3 mg/ml
The following instructions explain how to inject Omnitrope 3.3 mg/ml yourself. Please read the instructions carefully and follow them step by step. Your doctor or other suitably qualified health professional will show you how to inject Omnitrope. Do not attempt to inject unless you are sure you understand the procedure and requirements for 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).

Preparation
Collect necessary items before you begin:
- a cartridge with Omnitrope 3.3 mg/ml solution for injection.
- the Omnitrope Pen 5, an injection device specifically developed for use with Omnitrope 3.3 mg/ml solution for injection (not supplied in the pack; see Instructions for Use provided with the Omnitrope Pen 5).
- a pen needle for subcutaneous injection.
- 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 stop using Omnitrope

A disruption or early ending of treatment with somatropin may impair the success of growth hormone therapy. Please ask your doctor for advice before stopping treatment.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Omnitrope can cause side effects, although not everybody gets them.

Please ask your doctor for advice when you experience any of the symptoms described below.

	Common (occurring in at least 1 of 100 but less than 1 of 10 patients)	Uncommon (occurring in at least 1 of 1,000 but less than 1 of 100 patients)	Rare (occurring in at least 1 of 10,000 but less than 1 of 1,000 patients)	Very Rare (occurring in less than 1 of 10,000 patients)
General disorders and reactions at the injection site	In infants/ children/ adolescents: transient local skin reactions In adults: mild oedema	In infants/ children/ adolescents: mild oedema		
Musculoskeletal system, connective tissues, bones	In adults: stiffness of the limbs, joint and muscle pain	In infants/ children/ adolescents: stiffness of the limbs, joint and muscle pain		
Nervous system	In adults: sensory disturbances	In infants/ children/ adolescents: sensory disturbances In adults: carpal tunnel syndrome	Benign intracranial hypertension	
Endocrine disorders			Diabetes mellitus	
Disorders of the immune system	Development of antibodies			
Benign and malignant neoplasms				Leukemia

General disorders and reactions at the injection site

- Temporary local reactions at the injection site, such as pain, numbness, reddening, and swelling are common side effects. In isolated cases, subcutaneous administration of somatropin can lead to loss of fatty tissue at the injection site.
- Mild oedema (accumulation of water in the tissues) has been observed. This side effect is a consequence of disturbances in fluid balance and occurs only at the start of treatment with somatropin and is dose-dependent. It is common in adult patients, but uncommon in infants, children and adolescents.

Musculoskeletal system, connective tissues, and bones

- Joint and muscle pain (especially in the hip or knee) and stiffness of the limbs have been observed. These side effects occur only at the start of treatment with somatropin and are dose-dependent. They are common in adult patients, but uncommon in infants, children and adolescents.

Nervous system

- Sensory disturbances, such as numbness and tingling, have been observed. These usually occur at the start of treatment with somatropin and are dose-dependent. They are common in adult patients, but uncommon in infants, children and adolescents.
- Muscular atrophy (reduction of muscular tissue) of the ball of the thumb and sensory disturbances in the fingers and palm of the hand are uncommon side effects. They are consequences of carpal tunnel syndrome (constriction of the nerve supplying part of the palm of the hand), which has been observed mainly in adults.
- Visual disturbances, headaches, nausea, and vomiting have been observed. These symptoms could indicate benign intracranial hypertension (increased brain pressure), which is a rare side effect of treatment with somatropin.

Endocrine disorders

- Diabetes has been observed as a rare side effect.

Disorders of the immune system

- As with all protein based medicines, some patients may develop antibodies to the protein. However, these have not been found to have growth-inhibiting effects. This is a common side effect.

Benign and malignant neoplasms

- Very rare cases of leukemia have been reported in growth-hormone deficient children treated with somatropin. A causal relationship to somatropin therapy is unlikely.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE OMNITROPE

Keep out of the reach and sight of children.

Do not use after the expiry date which is stated on the label and carton. 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 it was frozen or subject to high temperatures.
Do not use Omnitrope if you notice that the solution is cloudy.

6. FURTHER INFORMATION

What Omnitrope contains

The active substance of Omnitrope is somatropin (3.3 mg/ml) in a cartridge.
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 looks like and contents of the pack
Omnitrope is presented as a solution for injection.
Pack sizes of 1, 5 or 10.
Omnitrope is a clear and colourless solution.
Not all pack sizes may be marketed.

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Detailed information on this medicine is available on the European Medicines Agency (EMEA) web site: http://www.emea.europa.eu

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