Patient Information Leaflet

SCHEDULING STATUS:

S5

PROPRIETARY NAMES, STRENGTHS AND PHARMACEUTICAL FORM:

OMNITROPE 5 mg/1,5 mℓ (solution for injection)

OMNITROPE 10 mg/1,5 mℓ (solution for injection)

OMNITROPE 15 mg/1,5 mℓ (solution for injection)

Read all of this leaflet carefully before you start using OMNITROPE:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- OMNITROPE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT OMNITROPE CONTAINS:

Active:

Omnitrope 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).

Omnitrope 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).

Omnitrope 15 mg/1,5 mℓ: Each mℓ of solution contains 10 mg of somatropin (corresponding to 30 IU). One cartridge contains 1,5 mℓ corresponding to 15 mg somatropin (45 IU).

Other ingredients:

Omnitrope 5 mg/1,5 mℓ: Benzyl alcohol, disodium hydrogen phosphate heptahydrate, mannitol, poloxamer 188, sodium dihydrogen phosphate dehydrate, water for injection. Each mℓ contains 9 mg benzyl alcohol.

Omnitrope 10 mg/1,5 mℓ: Disodium hydrogen phosphate heptahydrate, glycine, phenol, poloxamer 188, sodium dihydrogen phosphate dehydrate, water for injection.
Omnitrope 15 mg/1,5 mℓ: Disodium hydrogen phosphate heptahydrate, phenol, poloxamer 188, sodium dihydrogen phosphate dehydrate, sodium chloride, water for injection.

Omnitrope 5 mg/1,5 mℓ (solution for injection) contains mannitol.

Contains preservatives:

Omnitrope 5 mg/1,5 mℓ contains benzyl alcohol 0,9 *% m/v.*

Omnitrope 10 mg/1,5 mℓ contains phenol 0,3 *% m/v.*

Omnitrope 15 mg/1,5 mℓ contains phenol 0,3 *% m/v.*

2. WHAT OMNITROPE 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’s syndrome. Turner’s syndrome is a genetic disorder in girls that can affect growth - your doctor would 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.

3. BEFORE YOU USE OMNITROPE:

Do not use OMNITROPE:

- If you are allergic (hypersensitive) to somatropin or to any of the other ingredients of OMNITROPE (see “WHAT OMNITROPE CONTAINS”).
- Tell your doctor if 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.
- To stimulate growth if growing is already finished (closed epiphyses).
- If you are seriously ill (for example, complications following open-heart surgery, abdominal surgery, accidental trauma, acute respiratory failure, or similar conditions).
- If you or the child you are caring for are about to have, or have had, a major operation, or have to go into hospital for any reason, tell your doctor and remind other doctors you are seeing that you or the child you are caring for are using growth hormone.

Take special care with OMNITROPE:

- If you are at risk of developing diabetes, your doctor will need to monitor your blood sugar level during therapy with OMNITROPE.
- 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 he needs to change the dose of your medicines to treat diabetes.
- After starting OMNITROPE treatment, some patients may need to start thyroid hormone replacement therapy.
- 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 walk with a limp or if you start to limp during your growth hormone treatment, you should inform your doctor.
- If you are receiving OMNITROPE for growth hormone deficiency following a previous tumour (cancer), you should be examined regularly for recurrence of the tumour.
- If you are HIV (Human Immunodeficiency Virus) positive. The safety of use of somatropin in patients affected by HIV has not been established.

There may be an increased risk of developing an inflammation of the pancreas (pancreatitis) in children compared to adults treated with somatropin. Although rare, pancreatitis should be considered in OMNITROPE treated children who develop abdominal pain.

Children with chronic renal (kidney) insufficiency:

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

Pregnancy and breastfeeding:

You should not use OMNITROPE if you are pregnant or trying to become pregnant. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Important information about some of the ingredients of OMNITROPE:

OMNITROPE 5 mg/1,5 mℓ: 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.

Taking other medicines with OMNITROPE:

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicine). Especially tell your doctor, pharmacist or healthcare provider if you take:

- medicine to treat diabetes,
- thyroid hormones,
- medicine to control epilepsy (anticonvulsants),
- ciclosporin (a medicine that weakens the immune system after transplantation),
- sex hormones (for example oestrogens),
- synthetic adrenal hormones (corticosteroids).

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

4. 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 meters (m^2), as well as your treatment schedule. Do not change the dosage and treatment schedule without consulting your doctor.

OMNITROPE injection with SurePal pen:

- 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. 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 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 the 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.
- 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 SurePal. 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 inject, 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 safely. 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.

Effects when treatment with OMNITROPE is stopped:

Ask your doctor for advice before you stop using OMNITROPE.

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

5. POSSIBLE SIDE EFFECTS:

Like all medicines, OMNITROPE can cause side effects, although not everybody gets them. Not all side effects reported for OMNITROPE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Frequent side effects include:

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

In children:

Temporary reddening, itchiness or pain at the injection site.

Less frequent side effects include:

In children:

- Numbness/tingling.
- Stiffness in the arms and legs, joint pain, muscle pain.
- Water retention (which shows as puffy fingers or swollen ankles, for a short time at the start of treatment).

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.

6. STORAGE AND DISPOSAL OF OMNITROPE:

KEEP OUT OF REACH AND SIGHT 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 (dispose) any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

7. PRESENTATION OF OMNITROPE:

Omnitrope 5 mg/1,5 mℓ: 1,5 mℓ of solution in a cartridge (colourless type I glass) with a grey plunger on one side (siliconised bromobutyl), a grey disc (bromobutyl) and a gold cap

(aluminium) on the other side. The glass cartridge is irreversibly integrated in a transparent container and assembled to a plastic mechanism with a threaded rod at one extremity.

Omnitrope 10 mg/1,5 mℓ: 1,5 mℓ of solution in a cartridge (colourless type I glass) with a grey plunger on one side (siliconised bromobutyl), a grey disc (bromobutyl) and a silver cap (aluminium) on the other side. The glass cartridge is irreversibly integrated in a transparent container and assembled to a plastic mechanism with a threaded rod at one extremity.

Omnitrope 15 mg/1,5 mℓ: 1,5 mℓ of solution in a cartridge (colourless type I glass) with a grey plunger and a blue ring on one side (siliconised bromobutyl), a grey disc (bromobutyl) and a silver cap (aluminium) on the other side. The glass cartridge is irreversibly integrated in a transparent container and assembled to a plastic mechanism with a threaded rod at one extremity.

Omnitrope is packed into an outer cardboard carton in pack sizes of 1, 5 or 10.
Not all pack sizes may be marketed.

8. IDENTIFICATION OF OMNITROPE:

Omnitrope 5 mg/1,5 mℓ: The solution is clear and colourless. Solution for injection in a cartridge for SurePal 5.
Omnitrope 10 mg/1,5 mℓ: The solution is clear and colourless. Solution for injection in a cartridge for SurePal 10.
Omnitrope 15 mg/1,5 mℓ: The solution is clear and colourless. Solution for injection in a cartridge for SurePal 15.

Omnitrope solution for injection is practically free from visible particulate matter.

9. REGISTRATION NUMBERS:

Omnitrope 5 mg/1,5 mℓ: 49/21.10/0735.732

Omnitrope 10 mg/1,5 mℓ: 49/21.10/0736.733

Omnitrope 15 mg/1,5 mℓ: 49/21.10/0737.734

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Sandoz SA (Pty) Ltd.[1]

72 Steel Road, Spartan

Kempton Park, 1619

11. DATE OF PUBLICATION:

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