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EPAR summary for the public

Omnitrope

somatropin

This is a summary of the European public assessment report (EPAR) for Omnitrope. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Omnitrope.

For practical information about using Omnitrope, patients should read the package leaflet or contact their doctor or pharmacist.

What is Omnitrope and what is it used for?

Omnitrope is a medicine used to treat children who:

- do not grow normally because they do not have enough growth hormone;
- are short because they have long-term kidney disease or a genetic disorder called Turner syndrome;
- are short and were born small for their gestational age, and have not caught up by the age of 4 years or later;
- have a genetic condition called Prader-Willi syndrome. Omnitrope is given to improve their growth and body composition (by reducing fat and improving muscle mass). The diagnosis must be confirmed by genetic testing.

Omnitrope is also used as replacement therapy in adult patients with pronounced growth hormone deficiency. The deficiency can have started in adulthood or childhood, and needs to be confirmed by testing before treatment.

Omnitrope contains the active substance somatropin and is a 'biosimilar' medicine. This means that Omnitrope is highly similar to a biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Omnitrope is Genotropin. For more information on biosimilar medicines, see here.

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How is Omnitrope used?

Omnitrope can only be obtained with a prescription and treatment should be started and monitored by a doctor experienced in the management of patients with growth disorders.

The medicine is available as a powder and solvent, which are made up into a solution for injection, or as a ready-to-use solution in a cartridge. It is given by injection under the skin, once a day. The patient or caregiver can inject Omnitrope, after being trained by a doctor or a nurse. The Omnitrope cartridges should only be used with the special Omnitrope injection device. The doctor calculates the dose for each patient individually according to the body weight and the condition being treated. The dose may need to be adjusted over time, depending on change in body weight and response to treatment.

For further information, see the package leaflet.

How does Omnitrope work?

Growth hormone is released by the pituitary gland (a gland at the base of the brain). It is important for growth during childhood and adolescence, and it also affects how the body handles proteins, fat and carbohydrates. The active substance in Omnitrope, somatropin, is identical to the human growth hormone, which it replaces. Somatropin is produced by a method known as 'recombinant DNA technology': the hormone is made by bacteria into which a gene (DNA) has been introduced that makes them able to produce somatropin.

What benefits of Omnitrope have been shown in studies?

Omnitrope was studied to show that it is comparable to the reference medicine, Genotropin. Omnitrope was compared with Genotropin in 89 children with a lack of growth hormone who had not been treated before. Results showed that, after treatment for 9 months, Omnitrope was as effective as Genotropin in improving growth. Children receiving Omnitrope and Genotropin grew at a similar rate of about 10.7 cm per year.

What are the risks associated with Omnitrope?

In adults, side effects related to fluid retention, such as peripheral oedema (swelling, especially of the ankles and feet), paraesthesia (numbness or tingling), joint and muscle pain, and stiffness of the limbs are common (may affect between 1 and 10 patients in 100). These side effects are uncommon in children (may affect between 1 and 10 patients in 1,000). As with all protein medicines, some patients may develop antibodies (proteins that are produced in response to Omnitrope). Howeve,r these antibodies do not have an effect on how well Omnitrope works. For the full list of side effects of Omnitrope, see the package leaflet.

Omnitrope must not be used if the patient has an active tumour or an acute life-threatening illness. It must also not be used for promoting growth in children with closed epiphyses (when the large bones have finished growing). For the full list of restrictions, see the package leaflet.

Why is Omnitrope approved?

The European Medicines Agency considered that, in accordance with EU requirements for biosimilar medicines, Omnitrope has been shown to have a comparable quality, safety and effectiveness to Genotropin. Therefore, the Agency's view was that, as for Genotropin, the benefit outweighs the identified risk and it recommended that Omnitrope be given marketing authorisation.

What measures are being taken to ensure the safe use of Omnitrope?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Omnitrope have been included in the summary of product characteristics and the package leaflet.

Other information about Omnitrope

The European Commission granted a marketing authorisation valid throughout the European Union for Omnitrope on 12 April 2006.

The full EPAR for Omnitrope can be found on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Omnitrope, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2018.