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EPAR summary for the public

Valtropin

somatropin

This is a summary of the European public assessment report (EPAR) for Valtropin. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Valtropin.

What is Valtropin?

Valtropin is a powder and solvent that are made up into a solution for injection. Valtropin contains the active substance somatropin.

Valtropin is a 'biosimilar' medicine. This means that Valtropin is similar to a biological medicine (the 'reference medicine') that is already authorised in the European Union (EU) and that Valtropin and the reference medicine contain the same active substance. The reference medicine for Valtropin is Humatrope. For more information on biosimilar medicines, see the question-and-answer document here.

What is Valtropin used for?

Valtropin is used to treat children in the following situations:

- children from two years of age and adolescents who fail to grow because they lack growth hormone (replacement therapy);
- children who are short because of Turner syndrome (a rare genetic disorder affecting girls), confirmed by chromosome analysis (DNA testing);
- children before puberty, who fail to grow because of longstanding kidney disease (chronic renal insufficiency).

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Valtropin is also used to treat adults with pronounced growth hormone deficiency, which has started in adulthood or childhood and needs to be confirmed by testing before treatment (replacement therapy).

The medicine can only be obtained with a prescription.

How is Valtropin used?

Valtropin treatment should be supervised by a doctor experienced in the management of patients with growth disorders. Valtropin is given by injection under the skin, once a day. The patient or caregiver can inject Valtropin after training by a doctor or a nurse. The doctor calculates the dose for each patient individually, depending on the body weight and condition, and may need to adjust it over time, depending on changes in body weight and response. The site of injection must be varied to avoid lipoatrophy (loss of fat below the skin).

How does Valtropin work?

Growth hormone is a substance secreted by a gland located at the base of the brain called the pituitary gland. It promotes growth during childhood and adolescence, and also affects the way the body handles proteins, fat and carbohydrates. The active substance in Valtropin, somatropin, is identical to human growth hormone. It is produced by a method known as 'recombinant DNA technology': the hormone is made by a yeast that has received a gene (DNA) that makes it able to produce somatropin. Valtropin replaces the natural hormone.

How has Valtropin been studied?

Valtropin was studied to show that it is comparable to the reference medicine, Humatrope. Valtropin was compared with Humatrope in 149 children with a lack of growth hormone and who had not been treated before. The study lasted 12 months, and measured the children's height at the beginning and the end of the study, and the speed of growth during the study.

What benefit has Valtropin shown during the studies?

After 12 months, treatment with Valtropin and Humatrope brought about similar increases in height and speed of growth (speed of +11.4 and +10.5 cm per year, respectively). This was considered sufficient to demonstrate that the benefits of Valtropin are comparable to those of the reference medicine.

What is the risk associated with Valtropin?

The most common side effects with Valtropin are reactions at the site of injection and hormonal changes, and, in adults, headache, paraesthesia (unusual sensation like pins and needles), arthralgia (joint pain) and joint disorders. For the full list of all side effects reported with Valtropin, see the package leaflet.

Valtropin should not be used in people who may be hypersensitive (allergic) to somatropin or any of the other ingredients (the solvent for Valtropin contains metacresol). Valtropin must not be used when the patient suffers from an active tumour, or a life-threatening illness. Valtropin must not be used for growth promotion in children with closed epiphyses (the state of the large bones when they have finished growing). For the full list of restrictions, see the package leaflet.

Why has Valtropin been approved?

The CHMP decided that, in accordance with EU requirements, Valtropin has been shown to have a comparable quality, safety and efficacy profile to Humatrope. Therefore, the CHMP's view was that, as for Humatrope, the benefit outweighs the identified risks.

Other information about Valtropin

The European Commission granted a marketing authorisation valid throughout the European Union for Valtropin to BioPartners GmbH on 24 April 2006. After five years, the marketing authorisation was renewed for a further five years.

The full EPAR for Valtropin 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 Valtropin, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2011.