



EUROPEAN MEDICINES AGENCY  
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## EPAR summary for the public

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# Somatropin Biopartners

## somatropin

This is a summary of the European public assessment report (EPAR) for Somatropin Biopartners. 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 Somatropin Biopartners.

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

### What is Somatropin Biopartners and what is it used for?

Somatropin Biopartners is a medicine that contains human growth hormone (also known as somatropin). It is used to treat children aged 2 to 18 years who are failing to grow normally because they do not have enough growth hormone. It is also used in adults with a lack of growth hormone who may have either had growth hormone deficiency as children or developed it later during adulthood.

### How is Somatropin Biopartners used?

Treatment with Somatropin Biopartners should be started and monitored by a doctor experienced in diagnosing and treating patients with growth hormone deficiency. The medicine can only be obtained with a prescription.

Somatropin Biopartners is available as a powder and solvent which are made into a suspension for injection. Somatropin Biopartners is injected under the skin once a week. The patient or caregiver can inject Somatropin Biopartners themselves, after training by a doctor or a nurse. In children, the recommended dose is 0.5 mg per kilogram body weight, injected once a week. In adults, the recommended dose is 2 mg injected once a week, except for female patients also taking oral oestrogen who should receive 3 mg once a week. The dose may need to be adjusted, depending on the patient's response to treatment and the side effects the patient experiences. For further information, see the package leaflet.



## How does Somatropin Biopartners work?

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

## What benefits of Somatropin Biopartners have been shown in studies?

Somatropin Biopartners has been studied in one main study involving 180 children with a lack of growth hormone. The study compared Somatropin Biopartners given once a week with another somatropin-containing medicine called Genotropin given once a day. The main measure of effectiveness was the increase in height of patients after one year of treatment. The study showed that Somatropin Biopartners was as effective as Genotropin at promoting growth: children receiving Somatropin Biopartners grew around 11.7 cm in one year, compared with 12.0 cm in children receiving Genotropin.

Somatropin Biopartners has also been studied in one main study involving 151 adults with growth hormone deficiency. This study compared Somatropin Biopartners with placebo (a dummy treatment) and measured the decrease in body fat (which is normally high in adults with growth hormone deficiency) after 6 months of treatment. Adults treated with Somatropin Biopartners had an average reduction of body fat of 1 kg while body fat in those treated with placebo increased by 0.5 kg.

## What are the risks associated with Somatropin Biopartners?

In children, the most common side effects with Somatropin Biopartners (which may affect more than 1 in 10 people) are injection site swelling and development of antibodies (proteins that are produced in response to Somatropin Biopartners). However, these antibodies do not seem to have an effect on the way the medicine works. In adults, the most common side effects (which may affect more than 1 in 10 people) are swelling, mild hyperglycaemia (high blood sugar levels) and headache. For the full list of all side effects reported with Somatropin Biopartners, see the package leaflet.

Somatropin Biopartners must not be used in patients with an active tumour or an acute life-threatening illness. For the full list of restrictions, see the package leaflet.

## Why is Somatropin Biopartners approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Somatropin Biopartners' benefits are greater than its risks and recommended that it be approved for use in the EU. The Committee concluded that Somatropin Biopartners is as effective in children who fail to grow normally as other somatropin-containing treatments given daily. In adults who lack growth hormone, Somatropin Biopartners has a modest effect in decreasing body fat. Regarding its safety, the side effects reported with Somatropin Biopartners were similar to those of other daily somatropin medicines, with the exception of increased injection site reactions in children, which should be balanced against the convenience of weekly injections.

## **What measures are being taken to ensure the safe and effective use of Somatropin Biopartners?**

A risk management plan has been developed to ensure that Somatropin Biopartners is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Somatropin Biopartners, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that markets Somatropin Biopartners will provide further long-term data on the effectiveness and safety of the medicine.

## **Other information about Somatropin Biopartners**

The European Commission granted a marketing authorisation valid throughout the European Union for Somatropin Biopartners on 05.08.2013.

The full EPAR for Somatropin Biopartners can be found on the Agency's website: [ema.europa.eu/Find/medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find/medicine/Human_medicines/European_public_assessment_reports). For more information about treatment with Somatropin Biopartners, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2013.