30 May 2013
EMA/CHMP/229455/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Somatropin Biopartners

somatropin

On 30 May 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Somatropin Biopartners, 2 mg, 4 mg, 7 mg, 10 mg and 20 mg, powder and solvent for prolonged-release suspension for injection intended for long-term treatment of growth failure in children and adolescents due to insufficient secretion of endogenous growth hormone, and as replacement therapy of endogenous growth hormone in adults with growth hormone deficiency (GHD). The applicant for this medicinal product is BioPartners GmbH. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Somatropin Biopartners is somatropin, a recombinant human growth hormone (rhGH) (H01AC01). The biological effects of somatropin are equivalent to those of human growth hormone (hGH) of pituitary origin.

In children with GHD, the main benefits with Somatropin Biopartners are its ability to stimulate the growth plates of long bones, and to promote cellular protein synthesis and nitrogen retention, resulting in an improvement in short- and long-term growth rates and an increase in height. In adults with GHD, somatropin, among other things, stimulates lipid metabolism and protein synthesis, resulting in a beneficial effect on body composition in that body fat stores are reduced and lean body mass is increased.

The most common side effects are injection site related reactions, peripheral oedema, headache, myalgia, arthralgia, paraesthesia, hypothyroidism and decreased free thyroxine.

A pharmacovigilance plan for Somatropin Biopartners will be implemented as part of the marketing authorisation.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8613
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

The approved indication is:

"Paediatric patients

Somatropin Biopartners is indicated for long-term treatment of growth failure in children (2 to 11 years old) and adolescents (12 to 18 years old) with an inadequate endogenous secretion of growth hormone.

Adult patients

Somatropin Biopartners is indicated for the replacement therapy of endogenous growth hormone in adults with childhood- or adult-onset growth hormone deficiency.

Adult-onset: Patients with growth hormone deficiency in adulthood are defined as patients with known hypothalamic-pituitary pathology and at least one additional known deficiency of a pituitary hormone not being prolactin. These patients should undergo a single dynamic test in order to diagnose or exclude a growth hormone deficiency.

Childhood-onset: In patients with childhood-onset isolated growth hormone deficiency (no evidence of hypothalamic-pituitary disease or cranial irradiation), two dynamic tests should be performed after completion of growth, except for those having low insulin-like growth factor-1 (IGF-1) concentrations (< -2 standard deviation score (SDS)), who may be considered for one test. The cut-off point of the dynamic test should be strict."

It is proposed that diagnosis and therapy with Somatropin Biopartners should be initiated and monitored by physicians adequately experienced in the diagnosis and management of patients with GHD.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Somatropin Biopartners and therefore recommends the granting of the marketing authorisation.