The European Agency for the Evaluation of Medicinal Products
Pre-Authorisation Evaluation of Medicines for Human Use

London, 26 June 2003
CPMP/3184/03

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS SUMMARY OF OPINION
for
OMNITROP

International Non-proprietary Name (INN): Somatropin

On 26 June 2003, the Committee for Proprietary Medicinal Products (CPMP) adopted a positive opinion, recommending to grant a marketing authorisation for the medicinal product OMNITROP 3.3 mg/ml solution for injection, intended for the treatment of growth disturbance in children (over three years of age) and adolescents due to insufficient secretion of growth hormone and growth disturbance associated with Turner syndrome or chronic renal insufficiency and as replacement therapy in adults with pronounced growth hormone deficiency. The applicant for this medicinal product is Sandoz GmbH.

The active substance of OMNITROP, somatropin, is manufactured by recombinant DNA technology. Somatropin is an anterior pituitary lobe hormone, ATC code H01AC01, which stimulates linear growth and increases the growth rate in children. In adults as well as in children, somatropin maintains a normal body composition by increasing nitrogen retention and stimulation of skeletal muscle growth, and by mobilisation of body fat.

The benefits of OMNITROP have been demonstrated by the efficacy results obtained with the liquid formulation, supportive clinical studies performed with a lyophilised formulation, and the results mentioned in literature for other, well-known, growth hormone containing products. It is concluded that the efficacy of OMNITROP parallels that of other growth hormone containing products. The overall design of the comparability programme has taken into account the nature of the molecule, the knowledge of the mode of action of the molecule and the experience with growth hormone in clinical use. The most common side effects are the development of antibodies to the protein without any growth-inhibiting effects, hypothyroidism, disturbances in fluid balance (oedema), arthralgia, myalgia, stiffness in the extremities, paraesthesia and transient local injection site reactions.

The approved indication for children (over three years of age) and adolescents is: “Growth disturbance due to insufficient secretion of growth hormone and growth disturbance associated with Turner syndrome or chronic renal insufficiency.” and for adults “Replacement therapy in adults with pronounced growth hormone deficiency as diagnosed in two different dynamic tests for growth hormone deficiency”.

It is proposed that the therapy with somatropin should be initiated and monitored by physicians who are experienced in the diagnosis and management of patients with growth hormone deficiency.
Detailed conditions for the use of this product will be described in the Summary of Product Characteristics (SPC), which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CPMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for OMNITROP and therefore recommends the granting of the marketing authorisation.

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