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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): somatropin

Procedure No. EMEA/H/C/PSUSA/00002772/201703

Period covered by the PSUR: 01/10/2015 - 31/03/2017

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for somatropin, the scientific conclusions of CHMP are as follows:

All products:

Based on available literature, higher doses of growth hormone are generally required during the initiation and maintenance phases of treatment in women with an intact hypothalamic-pituitary-gonadal axis and on oral oestrogens. Therefore, in order to achieve an equivalent clinical and biochemical response compared to men dose adjustments may need to be considered by the prescriber in female patients.

Omnitrope (MAH: Sandoz), Zomacton and associated names (MAH: Ferring), Norditropin and associated names (MAH: Novo Nordisk), Genotropin and associated names (MAH: Pfizer)

Based on available literature, hypothalamic-pituitary-adrenal axis can be affected and needs to be re-assessed during growth hormone therapy in growth hormone deficient patients, who were previously not found to be deficient in this axis. If necessary, glucocorticoid replacement should be initiated. In addition, patients already receiving glucocorticoid replacement therapy may need to have the dose of their replacement therapy adjusted, after somatropin treatment is initiated.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for somatropin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing somatropin is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.