15 December 2011
EMA/CHMP/965945/2011 Rev. 1*
Press Office

Press release

European Medicines Agency confirms positive benefit-risk balance of somatropin-containing medicines

Prescribers reminded to strictly follow approved indications and doses

Finalising its review of somatropin-containing medicines, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) confirms that the benefit-risk balance of these medicines remains positive. However, the CHMP wished to remind prescribers to strictly follow the approved indications and doses and to carefully consider the warnings and precautions for somatropin-containing medicines.

Somatropin is a human growth hormone, manufactured using recombinant DNA technology. It promotes growth during childhood and adolescence, and also affects the way the body handles proteins, fat and carbohydrates. It is used to treat a number of conditions associated with impaired growth and short stature. These include children who fail to grow adequately due to a lack of growth hormone, Turner syndrome, Prader-Willy syndrome or chronic renal insufficiency and short children born small for gestational age.

This review was initiated in December 2010 further to initial results from a long-term epidemiological study in patients treated with somatropin-containing medicines during childhood for idiopathic lack of growth hormone and idiopathic or gestational short stature. The study results suggested a possibly increased risk of mortality with somatropin therapy compared with the general population. In particular, an increased risk of mortality due to bone tumours and subarachnoid or intracerebral haemorrhage was observed.

In addition to the epidemiological study, the CHMP considered all available data on the safety of somatropin-containing medicines in its review, including data from clinical trials, registries, cohorts and from spontaneous reports of side effects, to assess the impact on the overall benefit-risk balance of these medicines.

* Prader-Willy syndrome added in paragraph two.

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The CHMP concluded that the study had significant methodological limitations and that the other safety data examined did not corroborate a potentially higher risk of mortality associated with somatropin-containing medicines.

Taking into account all available data, the Committee considered that the benefit-risk balance of somatropin-containing medicines remains positive in the approved indications and doses. The CHMP took the opportunity of this review to harmonise the existing contraindications, warnings and precautions for these medicines throughout the European Union. The harmonised wording emphasises that somatropin must not be used if there is any evidence of a tumour activity, and that the recommended maximum daily dose should not be exceeded.

The Committee will review any new important data on the safety of somatropin-containing medicines that may emerge and will communicate the outcome as appropriate.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. A question-and-answer document on this review is available on the Agency's website.
3. The reviews of the centrally authorised somatropin-containing medicines NutropinAq, Omnitrope and Valtropin, initiated at the request of the European Commission, were conducted under Article 20 of Regulation (EC) No 726/2004. More information on these medicines can be found in the European public assessment reports (EPARs) available on the Agency's website.
4. The review of nationally authorised somatropin-containing medicines, initiated at the request of France, was conducted under Article 107 of Directive 2001/83/EC. These medicines include Genotropin, Humatrope, Norditropin, Saizen and Zomacton.
5. The French safety study, 'Santé Adulte GH Enfant' (SAGhE), aimed at improving the knowledge on recombinant growth hormone and evaluating the health of young adults who have been treated during childhood with recombinant growth hormone. Using the compulsory France-Hypophyse national register, investigators of the SAGhE study identified more than 10,000 young adults who started a recombinant growth hormone treatment between 1985 and 1996. The available analysis covers approximately 7,000 of these patients.
   A new European safety and effectiveness SAGhE study was accepted for funding by the Seventh Framework Programme for Research and Technological Development, the EU's main instrument for funding research in Europe. The study is conducted by a European consortium of paediatric endocrinologist, epidemiologists and biostatisticians from eight EU countries. The study is still ongoing and further results, especially from the EU countries, are not likely to be available until 2012 at the earliest.
6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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