



INLAND EMPIRE HEALTH PLAN

PHARMACY TIMES

BY IEHP PHARMACEUTICAL SERVICES DEPARTMENT

January 12, 2011

Safety Warning: Growth Hormones

This letter is provided to inform you on December 22, 2010, a warning was released by the United States Food and Drug Administration (FDA) regarding the usage of recombinant human growth hormone (somatropin) in the medical field. The FDA was concerned with the possibility of earlier deaths for people who have taken somatropin.

This concern stemmed from preliminary findings by the Sante Adulte GH Enfant (SAGhE) study currently in progress in France. One of the main objectives for the investigators was to determine if mortality (overall and cancer-related) is increased in a population-based sample of adult individuals treated with growth hormone in childhood. A 30% increased risk of death with recombinant human growth hormone therapy compared to the general population in France was reported. There were 93 observed deaths in the treated group versus 70 expected deaths in France's general population. The data, however, indicated this result of increased death only associated with increased doses of recombinant growth hormone that are dosed at higher than what is normally prescribed for pediatric growth hormone deficiency, a maximum of 50mcg/kg/day. This higher dosage is also associated with increased bone tumors and cardiovascular diseases including stroke (mainly subarachnoid or intracerebral hemorrhage).

SAGhE is an observational epidemiological study that is scheduled to end on May 31, 2012. Its study population was based on a mandatory registry of patients in France who received somatropin treatment during childhood between 1985 and 1996 and whose vital status and cause of death was determined through September 2009.

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The FDA currently is actively examining the evidences for this matter and issues the following recommendations:

- FDA believes the benefits of recombinant growth hormone continue to outweigh its potential risks.
- Patients should continue their recombinant human growth hormone treatment as prescribed by their healthcare provider.
- A prescriber of recombinant human growth hormone should follow the recommended indications and doses in the product labels.
- Adverse events involving recombinant human growth hormone should be reported to the FDA MedWatch program at www.fda.gov/medwatch.

If you have any questions, please feel free to contact us at (909) 890-2067.

Sincerely,

IEHP Pharmaceutical Services

References:

1. US Food and Drug Administration. (2010, December 29). *Fda drug safety podcast for healthcare professionals: ongoing safety review of recombinant human growth hormone (somatropin) and possible increased risk of death*. Retrieved from <http://www.fda.gov/Drugs/DrugSafety/DrugSafetyPodcasts/ucm238349.htm>
2. SAGhE. (2010, August 1). *Safety and appropriateness of growth hormone treatments in europe saghe*. Retrieved from <http://saghe.aphp.fr/site/spip.php>