

Safety

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MedWatch The FDA Safety Information and Adverse Event Reporting Program

Safety Information

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Recombinant Human Growth Hormone (somatropin): Ongoing Safety Review - Possible Increased Risk of Death

[Posted 12/22/2010]

AUDIENCE: Pediatrics, Endocrinology

ISSUE: FDA is informing the public that results from a study conducted in France — the Santé Adulte GH Enfant (SAGhE) study — found that persons with certain kinds of short stature (idiopathic growth hormone deficiency and idiopathic or gestational short stature) treated with recombinant human growth hormone during childhood and who were followed over a long period of time, were at a small increased risk of death when compared to individuals in the general population of France. FDA is currently reviewing all available information on this potential risk and will communicate any new recommendations once it has completed its review.

BACKGROUND: Recombinant human growth hormone is a protein that is manufactured to be nearly identical to the main form of the naturally occurring human growth hormone. This hormone can stimulate tissue growth, linear growth (height), and protein, carbohydrate, lipid, and mineral metabolism. It has approved indications in both the adult and pediatric populations. In the United States, recombinant human growth hormone is used in the pediatric population to treat short stature due to growth hormone deficiency (including idiopathic [of unknown cause] growth hormone deficiency), Turner syndrome, Noonan syndrome, Prader-Willi syndrome, short stature homeobox-containing gene (SHOX) deficiency, chronic renal insufficiency, idiopathic short stature and children small for gestational age. Recombinant human growth hormone, also known as somatropin [rDNA origin] injection, is marketed under the following brand names in the United States: Genotropin, Humatrope, Norditropin, Nutropin, Nutropin AQ, Omnitrope, Saizen, and Tev-Tropin.

RECOMMENDATION: Do not stop taking recombinant human growth hormone without talking to your healthcare professional. At this time, FDA believes the benefits of recombinant growth hormone continue to outweigh its potential risks.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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FDA Drug Safety Communication: Ongoing safety review of Recombinant Human Growth Hormone (somatropin) and possible increased risk of death

Safety Announcement

Additional Information for Patients

Additional Information for Healthcare Professionals

Data Summary

Safety Announcement

[12-22-2010] The U.S. Food and Drug Administration (FDA) is informing the public that results from a study conducted in France—the Santé Adulte GH Enfant (SAGhE) study—found that persons with certain kinds of short stature (idiopathic growth hormone deficiency and idiopathic or gestational short stature) treated with recombinant human growth hormone during childhood and who were followed over a long period of time, were at a small increased risk of death when compared to individuals in the general population of France. FDA is currently reviewing all available information on this potential risk and will communicate any new recommendations once it has completed its review.

At this time, FDA recommends that patients continue their recombinant human growth hormone treatment as prescribed by their healthcare provider.

Recombinant human growth hormone is a protein that is manufactured to be nearly identical to the main form of the naturally occurring human growth hormone. This hormone can stimulate tissue growth, linear growth (height), and protein, carbohydrate, lipid, and mineral metabolism. It has approved indications in both the adult and pediatric populations. In the United States, recombinant human growth hormone is used in the pediatric population to treat short stature due to growth hormone deficiency (including idiopathic [of unknown cause] growth hormone deficiency), Turner syndrome, Noonan syndrome, Prader-Willi syndrome, short stature homeobox-containing gene (SHOX) deficiency, chronic renal insufficiency, idiopathic short stature and children small for gestational age.

The SAGhE study is reported to be a long-term epidemiological study.¹⁻³ It was designed to assess the long-term mortality of patients treated with recombinant human growth hormone during childhood. The study population was based on a mandatory registry of patients in France who received recombinant human growth hormone treatment during childhood between 1985 and 1996 and whose vital status and cause of death was determined through September 2009.

Recombinant human growth hormone, also known as somatropin [rDNA origin] injection, is marketed under the following brand names in the United States: Genotropin, Humatrope, Norditropin, Nutropin, Nutropin AQ, Omnitrope, Saizen, and Tev-Tropin.

(see [Data Summary](#) below)

Additional Information for Patients and Caregivers

- Do not stop taking recombinant human growth hormone without talking to your healthcare professional.
- Discuss any questions or concerns about recombinant human growth hormone with your healthcare professional.
- Report any side effects you experience to the FDA MedWatch program using the information in the "Contact Us" box at the bottom of the page.

Additional Information for Healthcare Professionals

- At this time, FDA believes the benefits of recombinant growth hormone continue to outweigh its potential risks.
- If you prescribe recombinant human growth hormone, follow the recommended indications and doses in the product labels.
- Report adverse events involving recombinant human growth hormone to the FDA MedWatch program, using the information in the "Contact Us" box at the bottom of the page

Data Summary

FDA is aware of the results of a long-term epidemiological study called SAGhE (Santé Adulte GH Enfant), which was designed to assess the long-term mortality of patients treated with recombinant human growth hormone during childhood.¹⁻³ This study was based on a mandatory registry of patients in France treated with recombinant growth hormone during childhood between 1985 and 1996.

The investigators report a 30% increased risk of death with recombinant human growth hormone therapy compared to the general population, with 93 observed deaths in the treated group versus 70 expected deaths in the general population in France. The data suggest an increase in mortality due to bone tumors and cardiovascular diseases including cerebrovascular events (mainly subarachnoid or intracerebral hemorrhage).

The risk of death was reported to be increased when doses of recombinant growth hormone that are higher than what is normally prescribed for pediatric growth hormone deficiency were used. The approved doses in the United States for pediatric growth hormone deficiency are below 50 mcg/kg/day, except during puberty, when a higher dose regimen is approved for a limited duration of time. For short stature indications other than growth hormone deficiency, doses up to 69 mcg/kg/day (0.48 mg/kg/week) are currently approved.

In summary, the SAGhE study reported an increased risk of death in patients who were treated with recombinant human growth hormone during childhood when compared to individuals in the general population of France. FDA is currently reviewing all available new information on this potential risk and at this time, recommends caution when interpreting the reported results. Additionally, FDA believes the benefits of recombinant growth hormone continue to outweigh the potential risks. Patients should continue to follow the advice of their healthcare provider. FDA will communicate with the public as soon as we have completed our evaluation. Further information is available in the European Medicines Agency (EMA) press releases^{1,3} and the Agence Francaise de Securite Sanitaire des Produits de Sante (AFSSAPS) press release (in French).²

1. [European Medicines Agency to review the safety of somatropin-containing medicines. December 10, 2010](#) (press release). Accessed on December 13, 2010
2. [Recombinant growth hormone \(recombinant somatropin\); first results of the long-term epidemiological study SAGhE. Agence Francaise de Securite Sanitaire des Produits de Sante, December 10, 2010](#) (press release). Accessed on December 13, 2010.
3. [European Medicines Agency. Update on somatropin-containing medicines; Review of somatropin officially started. December 16, 2010](#) (press release). Accessed on December 18, 2010.

Related Information

- [European Medicines Agency to review the safety of somatropin-containing medicines. December 10, 2010](#)
- [Recombinant growth hormone \(recombinant somatropin\); first results of the long-term epidemiological study SAGhE. Agence Francaise de Securite Sanitaire des Produits de Sante, December 10, 2010](#)
- [European Medicines Agency. Update on somatropin-containing medicines; Review of somatropin officially started. December 16, 2010](#)
- [Somatropin Information](#)

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