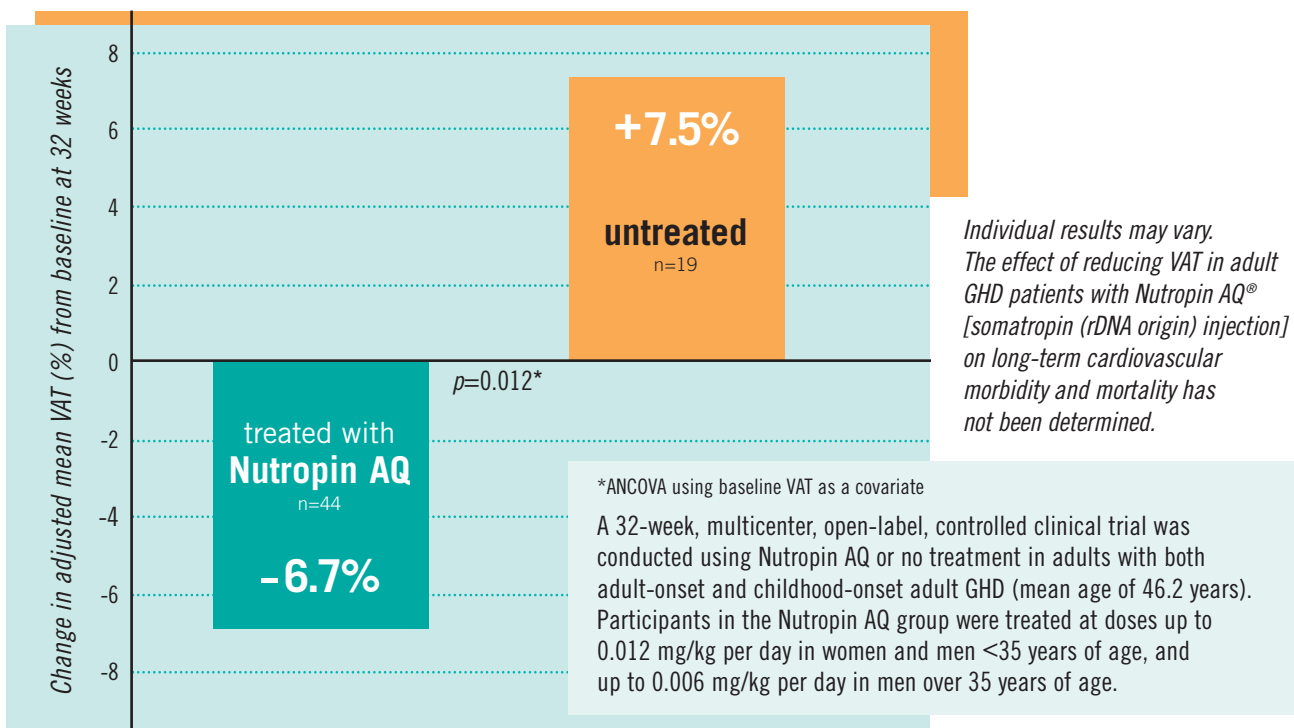


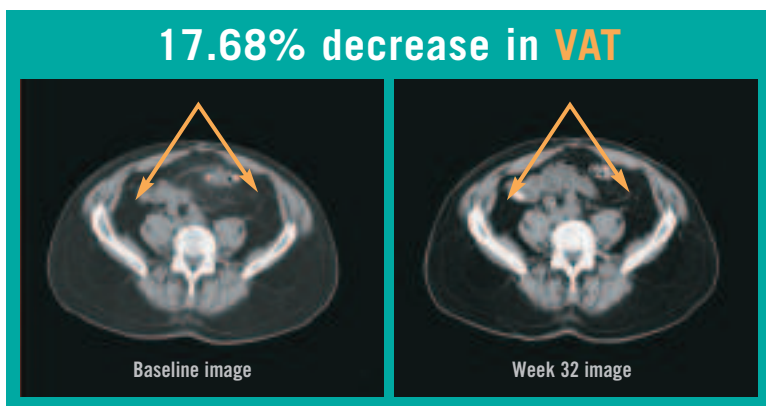
## Adult GHD Study Results:

# Nutropin AQ reduces visceral adipose tissue (VAT)<sup>1</sup>

## Approximately 14% difference between treated and untreated patients



## Abdominal scans demonstrate a significant reduction in VAT<sup>2</sup>



In this particular study subject, a reduction in VAT of 17% between baseline and week 32 of Nutropin AQ therapy was quantified in the patient's abdominal computed tomography (CT) scans.

### References:

1. Nutropin AQ<sup>®</sup> [somatropin (rDNA origin) injection] package insert. So. San Francisco, CA: Genentech, Inc.; 2005.
2. Hoffman AR, Biller BM, Cook D, et al. Efficacy of a long-acting growth hormone (GH) preparation in patients with adult GH deficiency. *J Clin Endocrinol Metab.* 2005;90:6431-6440.

**Nutropin AQ Pen<sup>®</sup> 10**  
for use with **Nutropin AQ Pen<sup>®</sup> 10 mg Cartridge**  
[somatropin (rDNA origin) injection]

**Nutropin AQ<sup>®</sup>**  
[somatropin (rDNA origin) injection]

**Nutropin<sup>®</sup>**  
[somatropin (rDNA origin) for injection]

Please see reverse side for indication and important safety information.

## Indication

Nutropin AQ® [somatropin (rDNA origin) injection] and Nutropin® [somatropin (rDNA origin) for injection] are indicated for the replacement of endogenous GH in patients with adult GHD who meet both of the following two criteria:

1. Biochemical diagnosis of adult GHD by means of a subnormal response to a standard growth hormone stimulation test (peak GH  $\leq 5$   $\mu\text{g/L}$ ), and
2. Adult-onset: Patients who have adult GHD either alone or with multiple hormone deficiencies (hypopituitarism) as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma; or Childhood-onset: Patients who were GH-deficient during childhood, confirmed as an adult before replacement therapy with Nutropin AQ or Nutropin is started.

## Contraindications

GH therapy should not be initiated to treat patients with acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma, or to patients having acute respiratory failure.

Nutropin AQ and Nutropin should not be used in patients with active neoplasia. GH therapy should be discontinued if evidence of neoplasia develops.

## Precautions

### General

Nutropin AQ and Nutropin should be prescribed by physicians experienced in the diagnosis and management of patients with adult GH deficiency.

Experience in prolonged rhGH treatment in adults is limited.

Because GH may reduce insulin sensitivity, patients should be monitored for signs of glucose intolerance. For patients with diabetes mellitus, insulin dosage may require adjustment when GH therapy is instituted.

Patients with a history of an intracranial lesion should be examined frequently for progression or recurrence of the lesion.

Intracranial hypertension (IH) with papilledema, visual changes, headache, nausea, and/or vomiting has been reported in a small number of patients treated with GH products. Symptoms usually occurred within the first 8 weeks of the initiation of GH therapy. In all reported cases, IH-associated signs and symptoms resolved after termination of therapy or a reduction of the GH dose. Fundoscopic examination of patients is recommended at the initiation and periodically during the course of GH therapy.

As with any protein, local or systemic allergic reactions may occur. Prompt medical attention should be sought if allergic reactions occur.

Careful monitoring is advisable when GH is given in combination with agents metabolized by CP450 liver enzymes.

### *Carcinogenesis, Mutagenesis, Impairment of Fertility*

Carcinogenicity, mutagenicity, and reproduction studies have not been conducted with Nutropin AQ or Nutropin.

GH should be given to a pregnant woman only if clearly needed, and caution should be exercised when administered to a nursing mother.

## Additional Safety Information

Thirty-five percent of childhood-onset adult GHD subjects treated with GH [0.025 mg/kg/d] for two years had supraphysiological levels of insulin-like growth factor-I (IGF-I) at some time during the study, which may carry unknown risks. During therapy, dosage should be decreased if required by the occurrence of side effects or excessive IGF-I levels.

Other adverse drug reactions that have been reported in GH-treated patients include the following:

- 1) Metabolic: mild, transient peripheral edema. In GHD adults, edema or peripheral edema was reported in 41% of GH-treated patients and 25% of placebo-treated patients; 2) Musculoskeletal: arthralgias; carpal tunnel syndrome. In GHD adults, arthralgias and other joint disorders were reported in 27% of GH-treated patients and 15% of placebo-treated patients; 3) Skin: rare increased growth of pre-existing nevi; patients should be monitored for malignant transformation; and 4) Endocrine: gynecomastia. Rare pancreatitis.