



Nutropin AQ and Nutropin  
**THE RIGHT DOSE AT  
THE RIGHT TIME**

**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]

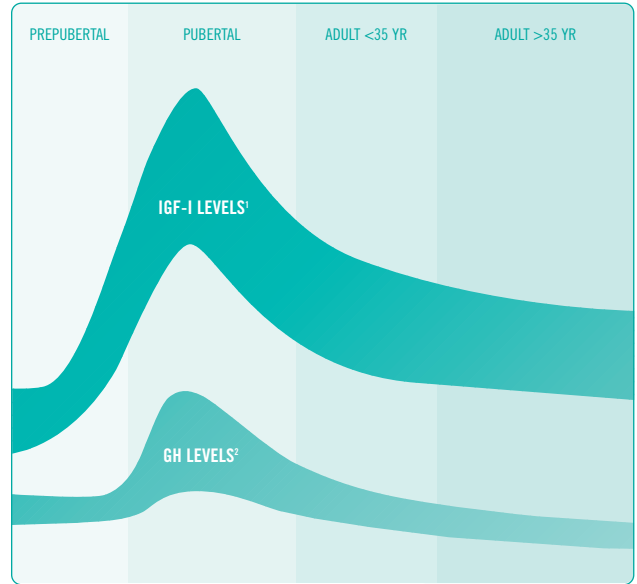
**Nutropin<sup>®</sup>**  
[somatropin (rDNA origin) for injection]

# THE ROLE OF GROWTH HORMONE THROUGHOUT LIFE

Endogenous growth hormone (GH) influences the metabolism of proteins, carbohydrates, and lipids as well as a child's growth. GH also plays an important role in maintaining normal body composition and metabolism throughout life.<sup>1-3</sup>

Patients with a lack of endogenous GH can be diagnosed at any age and GH is secreted at varying levels depending on their stage in life. For these patients, the goal of replacement therapy is to replace what is missing — with the right dose at the right time.

GH and IGF-I Dynamics Throughout the Normal Life Span<sup>4,5</sup>



GH plays an important role in maintaining normal body composition and metabolism throughout life.<sup>1-3</sup>

GH replacement therapy can be a lifetime commitment.

Please see accompanying Nutropin AQ and Nutropin full prescribing information.

Please see pages 6–7 for important safety information.

## Nutropin AQ and Nutropin THE RIGHT DOSE AT THE RIGHT TIME.



Early diagnosis and intervention provide the best opportunity for therapeutic success.<sup>6</sup> For prepubertal patients, daily administration of a fixed dosage of Nutropin AQ<sup>®</sup> [somatropin (rDNA origin) injection] or Nutropin<sup>®</sup> [somatropin (rDNA origin) for injection] of 0.3 mg/kg/wk is associated with optimal growth.<sup>7,8</sup>



As children enter puberty, the GH dose should be increased to approximate the natural rise in GH secretion that occurs in adolescence. In pubertal patients, a Nutropin AQ or Nutropin dosage of up to 0.7 mg/kg/wk is recommended.<sup>7,8</sup>



During the transition into adulthood, patients who were treated for GHD as children should be evaluated and, if appropriate, a new dose prescribed. For patients under 35 years of age, the recommended dosage of Nutropin AQ or Nutropin is up to 0.175 mg/kg/wk.<sup>7,8</sup>



The goal of adult GH therapy is to normalize physiologic function by maintaining GH at an age-adjusted level.<sup>9</sup> For GH-deficient adults over 35 years of age, the recommended Nutropin AQ or Nutropin dosage is 0.0875 mg/kg/wk.<sup>7,8</sup>

*Please see accompanying Nutropin AQ and Nutropin full prescribing information.*

*Please see pages 6–7 for important safety information.*

## INDICATIONS AND USAGE

Nutropin AQ® [somatropin (rDNA origin) injection] and Nutropin® [somatropin (rDNA origin) for injection] are indicated in pediatric patients for the long-term treatment of growth failure due to a lack of adequate endogenous GH secretion.

Nutropin AQ and Nutropin are also 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.

## IMPORTANT SAFETY INFORMATION

Your healthcare professional is your primary source of information. Discuss the potential benefits and risks of growth hormone (GH) treatment with your endocrinologist so you are familiar with possible side effects.

If the patient is treated at the hospital for any reason, notify your healthcare professional, including your endocrinologist, immediately.

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

It is important to notify the doctor if allergic reactions occur, such as itching, rash, redness, or swelling at the injection site.

Should your child develop a limp or worsened curvature of the spine, or complain of hip or knee pain, notify your child's doctor.

If the patient has diabetes, consult the treating doctor, as GH may affect the body's response to insulin.

If the patient has symptoms of headache, visual changes, nausea, and/or vomiting notify your healthcare professional immediately.

Nutropin AQ and Nutropin should not be used in growth promotion in pediatric patients whose bone growth is completed.

Discuss all medications the patient is taking with the treating doctor, particularly corticosteroids (like prednisone or hydrocortisone), sex steroids (like estrogens or testosterone), seizure medication or cyclosporine.

In addition to pediatric growth hormone deficiency, if the patient has been diagnosed with Prader-Willi syndrome, GH should not be used if the patient is severely obese or has severe breathing problems. Consult the treating doctor for more information.

If the patient becomes pregnant while on GH therapy, notify your doctor immediately. If the patient is nursing an infant while on GH therapy, you should also notify your doctor immediately.

During your treatment with GH your doctor may perform blood tests periodically (once every few months) in order to be able to make adjustments to your GH dose. Certain proteins (like IGF-I) will be measured that are directly influenced by the amount of GH given to you. This is done for safety reasons, please ask your doctor about the details.

Especially during the first days/weeks of your treatment with growth hormone you may experience swelling of your hand and feet (edema). Also pain and swelling of your joints may occur. If you experience these side effects please bring them to the attention of your healthcare team right away. Most likely your doctor has already discussed the possibility of these side effects with you and told you they are temporary and respond well to stopping GH treatment for a while and then restart at a lower dosage of GH.

## References:

1. Guyton AC. *Textbook of Medical Physiology*. Philadelphia, Penn: WB Saunders, Co; 2000.
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3. Kacsoh B. *Endocrine Physiology*. McGraw-Hill; 2000.
4. Brabant G, von zur Mühlen A, Wüster C, et al. Serum insulin-like growth factor I reference values for an automated chemiluminescence immunoassay system: results from a multicenter study. *Hor Res*. 2003;60(2):53-60.
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6. Blethen SL, Baptista J, Kuntze J, Foley T, LaFranchi S, and Johanson A. Adult height in growth hormone (GH)-deficient children treated with biosynthetic GH. *J Clin Endocrinol Metab*. 1997;82:418-420.
7. Nutropin AQ® [somatropin (rDNA origin) injection] full prescribing information [package insert]. So. San Francisco: Genentech, Inc.; 2005.
8. Nutropin® [somatropin (rDNA origin) for injection] full prescribing information [package insert]. So. San Francisco: Genentech, Inc.; 2005.
9. Gharib H, et al. AACE clinical practice guidelines for growth hormone use in adults and children. *Endocr Pract*. 1998;4(3):165-173.

The Nutropin AQ Pen is available in the US by prescription only.  
Healthcare professionals should provide patient training prior to use.

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