**Nutropin AQ® [somatropin (rDNA origin) injection]**

Nutropin AQ® is a recombinant human growth hormone (rhGH) available as a subcutaneous injection. This product is indicated for the treatment of patients with growth hormone (GH) deficiency in adults and children and for management of GH deficiency in patients with Prader-Willi Syndrome (PWS). It is also used for the treatment of short stature due to growth hormone (GH) deficiency in children. Nutropin AQ® is formulated in Thrandox® Aqueous PFS, which provides a clear, colorless, and odorless solution.

**Administration:**
- For adult patients, the recommended dose is 0.35 mg/kg daily or 0.7 mg/kg weekly divided into three doses per week. For children, the recommended dose is 0.2 to 0.4 mg/kg/wk.
- The injection should be given subcutaneously in the abdomen, upper arms, or thighs, avoiding the abdomen if possible.
- The injection site should be rotated every week to avoid localized irritation.

**Dosage and Administration:**
- The dosing schedule for children with GH deficiency is based on weight: 0.1 to 0.2 mg/kg weekly divided into three doses per week.
- For Prader-Willi Syndrome, the recommended dose is 0.3 to 0.4 mg/kg daily or 0.7 to 0.8 mg/kg weekly divided into three doses per week.
- The dose should be adjusted based on the patient's response and tolerated dose.

**Adverse Reactions:**
- Common side effects include injection site reactions, joint pain, headaches, and muscle pain.
- Rare side effects include hyperglycemia, carpal tunnel syndrome, and deep vein thrombosis.

**Contraindications:**
- Hypersensitivity to any component of the product.
- Patients with acromegaly.

**Precautions:**
- Close monitoring of blood glucose levels is essential in patients with diabetes mellitus.
- Patients with diabetes mellitus may require increased insulin or oral hypoglycemic agent doses.
- Patients with a history of cardiovascular disease should be monitored for signs of worsening cardiovascular disease.

**Special Populations:**
- Geriatric patients: The dosage should be based on the patient's response and tolerated dose.
- Pediatric patients: The dosage should be based on weight and response.

**Dosage Forms:**
- Vials: Each vial contains 10 mg of rhGH in a 2 mL solution.

**HOW SUPPLIED:**
- Each vial carton contains one single vial containing 2 mL of Nutropin AQ® [somatropin (rDNA origin) injection] 10 mg/2 mL cartridge for subcutaneous use. It is recommended that Nutropin AQ be of small enough volume that the prescribed dose can be drawn from the vial with reasonable accuracy.

**Nutropin AQ®**

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<th>Protocol-Defined Targeted Adverse Events in the ISS NCGS Cohort</th>
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**Boxed Warning:**
- There have been reports of fatalities after initiating therapy with somatropin in pediatric patients with Prader-Willi Syndrome who had one or more of the following risk factors: severe obesity, history of upper airway obstruction or sleep apnea, obstructive sleep apnea syndrome, or severe metabolic abnormalities.

**Safety and Tolerance:**
- Nutropin AQ therapy may be continued up to the time of renal transplantation.
- A weekly dosage of up to 0.35 mg/kg of body weight divided into daily subcutaneous injection is recommended.

**Legal Information:**
- The information provided is not intended to replace the advice of a qualified healthcare professional.

**References:**
- The references section provides additional information on the product, its use, and its side effects.

**Additional Information:**
- The additional information section provides further details on the product's use, dosage, and administration.

**Corporate Information:**
- The corporate information section provides information on the company that produces the product, as well as its contact information.

**Genentech, Inc.:**
- Address: 1089 Market Street, San Francisco, CA 94103
- Phone: 1-800-785-1040
- Website: [Genentech, Inc.](https://www.gene.com)

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**Last Updated:**
- The last updated date is important to note when referencing this information as it indicates when the information was last reviewed or updated.

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1. Introduction

Nutropin® is a purity, sterile, lyophilized powder intended for subcutaneous administration after reconstitution with sterile water for injection. The 5 mg and 10 mg vials of Nutropin® contain 5 mg (15 IU) and 10 mg (30 IU) of somatropin, respectively, lyophilized with mannitol and aprotinin (trypsin inhibitor). In a normal range than patients in the 0.3 mg/kg/wk group (27.7% vs. 9.0% of IGF-I measurements for individual patients).

2. Description

Each 5 mg Nutropin vial contains 5 mg (approximately 15 IU) somatropin, lyophilized with 45 mg mannitol, 1.7 mg sodium acetate, and 0.003 mg aprotinin. Each 10 mg Nutropin vial contains 10 mg (approximately 30 IU) somatropin, lyophilized with 90 mg mannitol, 3.4 mg sodium acetate, and 0.006 mg aprotinin. Nutropin® contains no genetically engineered growth hormone.

3. Precautions

3.1. General

Nutropin® should be used with caution in patients with a history of aseptic necrosis (AVN) and/or slipped capital femoral epiphysis (SCFE).

3.2. Patients with a history of aseptic necrosis and/or slipped capital femoral epiphysis

Patients with a history of AVN or SCFE may not receive continuous somatropin therapy.

3.3. Patients with diabetes

HbA1c levels remained in the normal range. In childhood-onset GH deficiency, the mean HbA1c level increased in the Nutropin group, while no change occurred in the placebo group. The mean HbA1c level was obtained at a mean age of 18.3 years in males and 17.3 years in females. The mean duration of therapy was 6.2 years in males and 5.6 years in females.

4. Adverse Reactions

4.1. General

In the adult-onset study, significant decreases from baseline to Month 12 in LDL cholesterol and LDL:HDL ratio were seen. The placebo group had mean changes of 0.6% or less (p = not significant).

4.2. Common

The most common adverse effect associated with somatropin therapy is injection site pain. These effects are generally mild to moderate and improve with time. Other common adverse effects associated with somatropin therapy include headache, joint pain, arthralgia, and back pain. These effects are generally mild to moderate and improve with time.

4.3. Exacerbation of pre-existing conditions

Children with growth failure secondary to CRI should be examined periodically for evidence of progression of renal failure.

4.4. Cardiovascular

In the adult-onset study, fluid retention during somatropin replacement therapy in adults may occur. Clinical signs and symptoms of fluid retention are generally mild to moderate, and transient. Serum cholesterol and triglyceride levels are generally increased.

4.5. Metabolism

Metabolism—Both the liver and kidney have been shown to be important metabolizing organs for GH. Animal studies demonstrate that somatropin injection results in a lag phase before any metabolic changes occur.

5. Indications

5.1. Growth Hormone Deficiency

Both short stature and idiopathic short stature (ISS) may respond to somatropin therapy, providing that the patients and their families are willing to accommodate the often large volume of intramuscular injections required.

6. Administration and Dosage

Dosage

6.1. Geriatric Patients

Alternatively, taking into account more recent literature, a starting dose of approximately 0.2 mg/day (range, 0.15–0.30 mg/day) is recommended for GH deficient adults. Fluid retention during somatropin replacement therapy in adults may occur. Clinical signs and symptoms of fluid retention are generally mild to moderate, and transient. Serum cholesterol and triglyceride levels are generally increased.

7. Dosage and Administration

7.1. Administration

Subcutaneous injection is the recommended route of administration. The optimal injection site is the anterior aspects of upper arms or abdomen. The injection site should be rotated.

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