



**MEDICINE PRODUCT LEAFLET:  
CONSUMER INFORMATION**

# Gen-Tropin AQx<sup>®</sup> 10mg(30IU)/3ml

**solution for injection in cartridges**

Somatropin

rHGH (recombinant human growth hormone)

**Please read this leaflet carefully before you start using this medicine.**

Do not throw away this leaflet as you may need to read it again. If you need more information please consult your doctor or pharmacist. This medicine is prescribed for personal use only. Do not share it with others even if the symptoms are the same. It may not be suitable for them and cause harm. Please notify your doctor or pharmacist immediately if any of the side effects become severe or if they are not mentioned in this leaflet.

**Information in this leaflet:**

1. What is Gen-Tropin AQx<sup>®</sup> and what it is prescribed for
2. Gen-Tropin AQx<sup>®</sup> contraindications
3. Gen-Tropin AQx<sup>®</sup> usage
4. Gen-Tropin AQx<sup>®</sup> possible side effects
5. Gen-Tropin AQx<sup>®</sup> storage
6. Other information.

**1. What is Gen-Tropin AQx<sup>®</sup> and what it is prescribed for**

Gen-Tropin AQx<sup>®</sup> contains a biosynthetic human growth hormone called somatropin.

Biosynthetic somatropin is identical to naturally produced growth hormone. Growth hormone is required for the children to grow. Adults need growth hormone for their general well-being. Gen-Tropin AQx<sup>®</sup> comes in a solution form, which is contained in a cartridge. It is ready for injections once you place it in the compatible pen.

**Gen-Tropin AQx<sup>®</sup> is used to treat growth deficiency in children in cases:**

- Short height due to SGA (small for gestational age).
- Kidney function affecting growth hormone levels
- Turner syndrome (genetic disease)
- If growth hormone production is abnormally low

**Gen-Tropin AQx<sup>®</sup> is used for growth hormone replacement therapies in adults:**

If pituitary gland production of growth hormone is decreased due to tumor, disease, surgery or if it is decreased since childhood, Gen-Tropin AQx<sup>®</sup> is then used to replace the lost production of natural growth hormone.

**2. Gen-Tropin AQx<sup>®</sup> contraindications**

**Do not use Gen-Tropin AQx<sup>®</sup> if you:**

- Have a cancer, a tumor or on therapy against tumor
- Have an had an acute respiratory failure, open heart or abdominal surgery.
- Have had a kidney transplant
- Are pregnant or breastfeeding
- Are allergic or hypersensitive to somatropin, or any of the other ingredients of Gen-Tropin AQx<sup>®</sup> (see section 6, Other information)

**Take special care with**

**Gen-Tropin AQx<sup>®</sup> If you**

- Have recurrent headaches, nausea, vomiting or eyesight problems,
- Have or ever had a cancer or a tumor
- Have abnormal thyroid function

- If you are over 60 years of age
- If you have a kidney disease
- Have diabetes
- Received growth hormone therapy for longer than 5 years as an adult

**Before using Gen-Tropin AQx<sup>®</sup> you must inform your doctor if any of the following applies to you.**

Tell your doctor if you are being treated with:

- **Insulin** your doctor may need to adjust a dose
- **Glucocorticoids** or **steroids** if you use Gen-Tropin AQx<sup>®</sup> with glucocorticoids or steroids, it may affect your height
- **Thyroid** hormone
- **Other medicine** this includes administration of any medicine without prescription or if you recently had taken any drug.

**Pregnancy and breastfeeding**

- **Breastfeeding.** Do not breastfeed while on Gen-Tropin AQx<sup>®</sup> therapy as somatropin may pass to your milk
- **Pregnancy.** If you became pregnant while taking Gen-Tropin AQx<sup>®</sup> stop the treatment and inform your doctor immediately

**Driving and operating machinery**

It is safe to drive or use any machinery while taking Gen-Tropin AQx<sup>®</sup>.

**3. Gen-Tropin AQx<sup>®</sup> usage**

Please follow a Gen-Tropin AQx<sup>®</sup> usage protocol exactly as was instructed by your doctor. If you are unsure about something, check with your doctor or pharmacist.

**Usual dose**

For children, dose depends on body surface area and their weight. For adults, dose depends on somatropin sensitivity, weight, height and gender.

Doctor may adjust your dose to find the right dose for you.

**Children:**

- **SGA (small for gestational age):** The usual dose is 35 microgram per kg body weight per day or 1.0 mg per m<sup>2</sup> body surface area per day until final height is reached.
- **Turner syndrome:** The usual dose is 45 to 67 microgram per kg body weight per day or 1.3 to 2.0 mg per m<sup>2</sup> body surface area per day.
- **Low production or lack of growth hormone:** The usual dose is 25 to 35 microgram per kg body weight per day or 0.7 to 1.0 mg per m<sup>2</sup> body surface area per day.
- **Kidney disease:** The usual dose is 50 microgram per kg body weight per day or 1.4 mg per m<sup>2</sup> body surface area per day.

**Adults:**

- **Low production or lack of growth hormone:** The usual starting dose is 0.1 to 0.3 mg per day. Your doctor will increase this dose each month until you are on the right dose. The usual maximum dose is 1.0 mg per day.

**When to use Gen-Tropin AQx<sup>®</sup>**

- Inject your daily dose under the skin every evening before bedtime.

**Using the cartridges to inject yourself**

- Gen-Tropin AQx<sup>®</sup> solution comes in cartridges ready to be placed in compatible pen and injected. See **Gen-Tropin AQx<sup>®</sup> Pen Instruction Manual** to find out how correctly use the cartridge with injection pen.
- Do not share your Gen-Tropin AQx<sup>®</sup> cartridge with other people.
- Do not use Gen-Tropin AQx<sup>®</sup> cartridge if the solution is not clear or colorless
- Check each Gen-Tropin AQx<sup>®</sup> cartridge before using it. If found cracked or damaged, do not use it.
- Change the injection area to avoid skin harm

## Treatment term

- continue using Gen-Tropin AQx<sup>®</sup> until you stop growing if you are using it for growth failure because of kidney disease, Turner syndrome or if you were born small for gestational age
- If you are still deficient in growth hormone, continue using Gen-Tropin AQx<sup>®</sup> into adulthood
- Discuss it with your doctor if you have any questions about cessation of Gen-Tropin AQx<sup>®</sup> therapy.

## If you use too much:

- Let your doctor know if you think you injected too much Gen-Tropin AQx<sup>®</sup>. Prolonged overdosing can cause coarsening of facial features or abnormal growth.

## If you forget a dose:

- Do not take a double dose. Just take the next dose as usual.

## 4. Gen-Tropin AQx<sup>®</sup> possible side effects

Gen-Tropin AQx<sup>®</sup> may cause side effects, however they are rare and very few develop them.

**Very rare effects** in children and adults (Occurrence 1 in 10,000 people):

- Signs of allergic reactions such as rash, wheezing, swollen eyelids, face or lips
  - Signs of increased brain blood pressure such as headache, nausea, eyesight problems or vomiting
  - Decrease of thyroxin levels in serum
- Stop using Gen-Tropin AQx<sup>®</sup> and see doctor as soon as possible if you note any of these side effects. Continue treatment if doctor allows it. Gen-Tropin AQx<sup>®</sup> therapy rarely observed to cause formation of somatotropin antibodies. Relapse of brain tumors and leukaemia were reported in patients undergoing somatotropin (the active ingredient in Gen-Tropin AQx<sup>®</sup>), although there is no evidence that somatotropin caused it. Speak to your doctor if you think you are suffering from any of these diseases.

## Other side effects in children:

### Uncommon effects

(Occurrence 1 in 100 children):

- Redness, itching and pain in the area of injection.
- Headache

### Rare effects

(Occurrence 1 in 1000 children):

- Swollen hands and feet due to fluid retention.
- Muscle and joint pain
- Rash

Rarely, while using Gen-Tropin AQx<sup>®</sup> children may develop hip or knee pain and start limping. These symptoms may be caused by LeggCalvé disease or femoral epiphysis, which are not due to Gen-Tropin AQx<sup>®</sup>. In few cases, during clinical trials, in children with Turner syndrome, hands and feet increase in growth not proportionally to their height.

High dose of Gen-Tropin AQx<sup>®</sup> may increase occurrence of ear infections.

## Other side effects in adults:

### Very common effects

(Occurrence 1 in 10 adults):

- Swollen hands and feet due to fluid retention.

### Common effects

(Occurrence 1 in 10 adults):

- Headache
- Feeling of skin crawling (formication) and numbness or pain mainly in fingers
- Joint pain and stiffness
- Muscle pain.

### Uncommon effects

(Occurrence 1 in 100 adults):

- Itching and pain in the area of injection
- Carpal tunnel syndrome tingling and pain in fingers and hands
- Type 2 diabetes
- Muscle stiffness.

Tell your doctor if any of these side effects gets serious, or if you notice any side effects not listed in this leaflet as you may need to reduce your dose.

## 5. Gen-Tropin AQx<sup>®</sup> storage

Keep out of the reach and sight of children. Do not use Gen-Tropin AQx<sup>®</sup> after the expiry date which is stated on the package. Store unused Gen-Tropin AQx<sup>®</sup> cartridges in a refrigerator (2°C to 8°C) in the outer carton, in order to protect from light. Do not freeze or expose to heat. After starting to use a Gen-Tropin AQx<sup>®</sup> 10mg/3ml cartridge in an injection pen you can keep it in the pen for up to 12 weeks in a refrigerator (2°C to 8°C). Do not continue to use Gen-Tropin AQx<sup>®</sup> cartridges which have been frozen or exposed to excessive temperatures. Check each new Gen-Tropin AQx<sup>®</sup> cartridge before you use it. Do not use any cartridge that is damaged or cracked. Do not use any Gen-Tropin AQx<sup>®</sup> cartridge if the solution inside is not clear and colorless. Due to environmental reasons, medicines should not be disposed of via household waste. Consult your pharmacist about how to dispose of medicines properly.

## 6. Other information

### What Gen-Tropin AQx<sup>®</sup> contains

- The active substance is somatotropin
- The solution also contains mannitol; histidine; poloxamer 188; phenol; water for injections; hydrochloric acid and sodium hydroxide.

### What Gen-Tropin AQx<sup>®</sup> looks like and contents of the pack

Gen-Tropin AQx<sup>®</sup> is a clear and colorless solution in a 3 ml glass cartridge ready for use with injection pen. 3 ml of solution contains 10 mg somatotropin. 1 mg of somatotropin corresponds to 3 IU of somatotropin. Gen-Tropin AQx<sup>®</sup> is available in one strength: 10mg(30IU)/3ml. For more information, please visit [www.gen-tropin-aqx.com](http://www.gen-tropin-aqx.com)

### Manufacturer

Gen-Tropin AQx<sup>®</sup> is made by:  
Bio-Gen pharma<sup>®</sup> Co., Ltd.  
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### Marketing authorization holder

Bio-Gen pharma<sup>®</sup> Co., Ltd.  
Marketing department  
Liuyang Bio-medical Park, Changsha, Hunan, China

**This leaflet was last approved in 02/2010.**

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