

PRODUCT MONOGRAPH

PrNUTROPIN AQ[®] NuSpin[®]

somatropin injection
solution; NuSpin[®] injection device prefilled with cartridge:

NUTROPIN AQ[®] NuSpin[®] 5 (5 mg/2 mL)
NUTROPIN AQ[®] NuSpin[®] 10 (10 mg/2 mL)
NUTROPIN AQ[®] NuSpin[®] 20 (20 mg/2 mL)

Growth Hormone

Distributed by:
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Genentech, Inc., USA

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PART III: CONSUMER INFORMATION**NUTROPIN AQ® NuSpin®**
somatropin injection

This leaflet is part III of a three-part "Product Monograph" published when NUTROPIN AQ was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about NUTROPIN AQ. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:****Children:**

- NUTROPIN AQ is used for the treatment of children with growth failure who are unable to produce adequate amounts of growth hormone (GH).
- NUTROPIN AQ may help children who have growth failure associated with chronic renal insufficiency (CRI) (up to the time of renal transplantation).
- NUTROPIN AQ may also help children who have growth failure associated with Turner syndrome. Turner syndrome is a genetic disorder associated with short stature and growth problems in girls.

Adults:

NUTROPIN AQ is used for the replacement of GH normally produced by the body in patients with adult GH deficiency who meet both of the following criteria:

1. Biochemical diagnosis of adult GH deficiency (by laboratory GH testing of blood), and
2. *Adult-onset:* Patients who became GH-deficient as adults, or
3. *Childhood onset:* Patients who were GH-deficient as children and continue to be so as adults. ⁶

What it does:

NUTROPIN AQ is used to increase growth hormone (GH) levels in children and adults unable to produce adequate amounts naturally. NUTROPIN AQ may produce bone growth in children where the ends of the long bones have not yet hardened. It may also cause other effects on the body. In both adults and children requiring growth hormone replacement, NUTROPIN AQ helps in the development of muscles and causes fat to be used for energy. In adults with GH deficiency, NUTROPIN AQ plays an important role in maintaining an improved ratio of body fat to lean mass, "bad" to "good" cholesterol levels, and proper bone mineral density.

When tested, GH levels may appear normal in girls with Turner syndrome, yet studies have shown that GH therapy improves growth despite this fact. GH treatment can help many girls with Turner syndrome increase the growth rate and achieve greater final height.

When it should not be used:

- If you / your child have acute critical illness due to complications following open-heart or abdominal surgery, multiple accidental trauma, or acute respiratory failure.
- If your child's growth areas of the bones have closed and cannot grow longer.
- You / your child have active cancer or tumors. Therapy with NUTROPIN AQ should be discontinued if evidence of cancer develops.
- You / your child have Prader-Willi syndrome and are severely obese or have severe respiratory problems. There have been reports of deaths in children with Prader-Willi syndrome who were treated with growth hormone and had one or more of the following risk factors: severely obese, history of blocked upper airways, sleep apnea (pauses in breathing while asleep), or other severe breathing problems.

What the medicinal ingredient is:

somatropin

Somatropin is a form of the naturally occurring human GH. Human GH is important in the body for the growth of bones and muscles.

What the non-medicinal ingredients are:

phenol, polysorbate 20, sodium chloride, sodium citrate

What dosage forms it comes in:

somatropin injection; solution, NuSpin injection device prefilled with cartridge:

- NUTROPIN AQ® NuSpin® 5 (5 mg/2 mL)
- NUTROPIN AQ® NuSpin® 10 (10 mg/2 mL)
- NUTROPIN AQ® NuSpin® 20 (20 mg/2 mL)

WARNINGS AND PRECAUTIONS

BEFORE you use NUTROPIN AQ talk to your doctor or pharmacist if:

For all patients

- You / your child have Prader-Willi syndrome and breathing problems, sleep apnea (pauses in breathing while asleep) or snoring.
- You / your child are experiencing headache, nausea, visual changes, and/or vomiting. You / your child may have a condition called intracranial hypertension.
- You / your child have a history of an intracranial lesion (a lesion/tumor of the brain) or childhood cancer.
- You / your child have diabetes since NUTROPIN AQ may affect your / your child's body's response to insulin. The insulin dose may require adjustment.
- You / your child have hypopituitarism.
- You / your child have hypothyroidism. NUTROPIN AQ may reduce the levels of thyroid hormone.

For pediatric patients

- Patients with growth failure in chronic renal insufficiency should have periodic checkups for a type of bone disease called renal osteodystrophy.
- Your child has a history of scoliosis (a condition which affects the spine). Because GH increases growth rate, patients with a history of scoliosis who are treated with NUTROPIN AQ should be monitored for progression of scoliosis.

For adult patients

- You are pregnant or nursing.

Clinical trial experience with prolonged growth hormone treatment in adults is limited.

INTERACTIONS WITH THIS MEDICATION

Glucocorticoids (steroids) may decrease the effects of NUTROPIN AQ. If you / your child are receiving concomitant glucocorticoid (steroid) therapy contact your doctor. Steroid doses may need to be adjusted.

NUTROPIN AQ may affect your / your child's body's response to insulin. Contact your doctor if you / your child have diabetes. It may be necessary to adjust the dosage of diabetes medications.

Oral estrogens may decrease the effects of NUTROPIN AQ. If you / your child are receiving oral estrogen replacement therapy, contact your doctor. Your / your child's NUTROPIN AQ dose may need to be adjusted.

Drugs other than those listed here may also interact with NUTROPIN AQ.

PROPER USE OF THIS MEDICATION

Usual dose:

Your doctor will calculate the dose of NUTROPIN AQ based on your / your child's body weight.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

Missing injections can interfere with the effectiveness of the medication. Talk to your doctor if this should happen. Do not try to make up for missed injections by "doubling up" on injections.

INFORMATION FOR THE PARENT/PATIENT

NUTROPIN AQ NuSpin

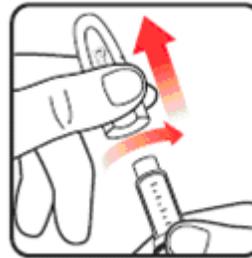
somatropin injection

Do not inject the drug until your doctor or nurse has thoroughly trained you in the proper techniques.

Your doctor or nurse will tell you what needle to use for giving the medication. Use the sterile technique as instructed by your doctor or nurse. Dispose of needles properly after each use, out of the reach of children. The NUTROPIN AQ NuSpin was designed to allow for simplified and accurate dose delivery.

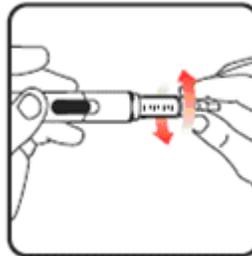
PREPARATION OF NuSpin:

ATTACH THE NEEDLE



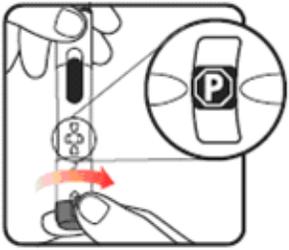
1. Wash your hands thoroughly. Gently twist and pull to remove the NuSpin cap. Inspect the cartridge before use to ensure that the medicine in it is clear. If it is cloudy or hazy, do not inject it.

Open a new needle by peeling off the paper tab from the needle package.



2. The NUTROPIN AQ NuSpin has prefilled cartridges so no reconstitution or preparation is required. Simply attach the needle by carefully screwing it onto the needle holder—do not over tighten. Carefully remove both protective covers from the needle and save the outer cover.

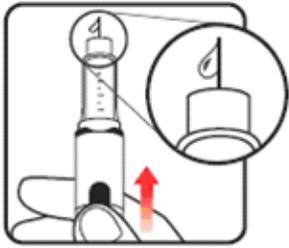
PRIMING THE NUTROPIN AQ NuSpin



3. Turn the dose knob to the “P” position in the dose window. It may take multiple clicks to get to “P”.

The “P” position represents a:

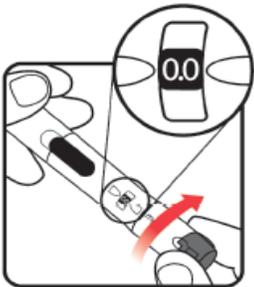
- 0.35 mg dose on the NUTROPIN AQ NuSpin 5
- 0.7 mg dose on the NUTROPIN AQ NuSpin 10
- 1.4 mg dose on the NUTROPIN AQ NuSpin 20



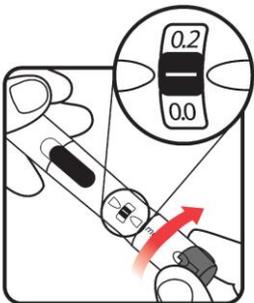
4. Hold the NuSpin with the needle pointing upwards. Gently tap the cartridge holder to move any air bubbles to the NuSpin tip.

Slide the Activator toward the needle. If you do not see fluid at the needle tip, redial to “P” and slide the Activator forward again. Repeat until you see fluid. When you do, you’re primed and ready to go.

SETTING THE DOSE



5. Make sure the dose window reads “0.0”. Then, turn the dose knob until the prescribed dose appears in the dose window. If you turn the dose knob too far, simply turn it back to the correct dose.



If your dose is “between” two numbers in the dose window, the “-” marking between those two numbers indicates your dose. The spinning dose knob allows you to choose the dose as prescribed by your doctor.

(Example on the left shows a dose of 0.1 mg on the NUTROPIN AQ NuSpin 10, represented by “-”).

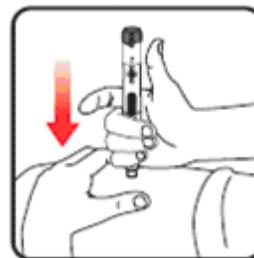
SELECTING THE INJECTION SITE

Your doctor or nurse will teach you how to locate appropriate injection sites. It is very important that you rotate the site of an injection each time you give the medication. Even if you / your child develop a preference for one site you still should rotate the injection site.

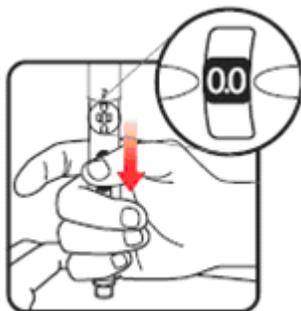
The following drawings indicate the injection sites most often recommended:

	<ul style="list-style-type: none"> • Upper Arm
	<ul style="list-style-type: none"> • Abdomen
	<ul style="list-style-type: none"> • Thigh

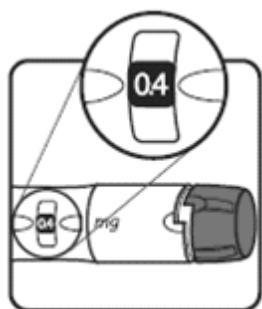
GIVING THE INJECTION



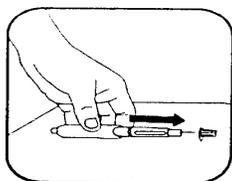
1. Once you’ve chosen the injection site and prepared it, put one hand where you can easily slide the Activator. While holding the NuSpin device, insert the needle into the skin by pushing downward until the appropriate depth is reached.



2. Slide the Activator toward the needle. The activator delivers the medication automatically. Continue to hold the Activator down until the dose knob returns to “0.0”. The time for each dose is relatively quick, and happens within approximately 5 seconds. It may help to count out loud for 5 seconds while you are holding the Activator down. Then, withdraw the NUTROPIN AQ NuSpin device. If the dose knob returns to “0.0”, this provides assurance that the full dose has been delivered.



3. If the dose knob stops before it returns to “0.0”, the NUTROPIN AQ NuSpin is empty and the full dose has not been delivered. The number shown in the dose window is the amount needed to obtain a full dose. (Ask your healthcare professional to walk you through the procedure for using the last dose in the NuSpin.) This spinning dose knob ensures that the dose delivered is the dose required.



4. Place the needle cap on a flat surface. Slide the needle in to pick it up and push the cap completely down over the needle. Twist off the needle and discard it properly.

Needle disposal

- Place all used needles in a hard, plastic container with a screw-on cap, or a metal container with a plastic lid, such as a coffee can properly labeled as to content. If a metal container is used, cut a small hole in the plastic lid and tape the lid to the metal container. When the metal container is full, cover the hole with tape. If a hard, plastic container is used, always screw the cap on tightly after each use. When the plastic container is full, tape around the cap. If you have any questions or concerns about the safe disposal of these materials, please call your doctor, nurse or pharmacist.
- Do not use glass or clear, plastic containers, or any container that will be recycled or returned to a store.
- Always store the container out of the reach of children.

- Please check with your doctor, nurse or pharmacist for other suggestions. There may be special provincial and local laws that they will discuss with you.

Next use

Replace the cap and store the NUTROPIN AQ NuSpin in the refrigerator at 2-8°C. Protect from light, and do not let it freeze.

For subsequent injections of the NUTROPIN AQ NuSpin, attach a new needle, dial in the dose, and give the injection.

YOU DO NOT NEED TO PRIME THE DEVICE UNLESS IT IS YOUR FIRST INJECTION WITH A NEW NuSpin.

Occasionally a problem may develop at the injection site. If you notice any of the following signs or symptoms, contact your doctor or nurse:

- A lump or swelling that doesn't go away.
- Bruising that doesn't go away.
- Any signs of infection or inflammation at an injection site (pus, persistent redness surrounding skin that is hot to the touch, persistent pain after the injection).

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The following side effects may occur while using NUTROPIN AQ:

- Rare cases of serious breathing problems have been reported in patients with Prader-Willi syndrome taking NUTROPIN AQ. Contact your doctor immediately if you / your child have Prader-Willi syndrome and develop signs of breathing problems, sleep apnea (pauses in breathing while asleep) or new or increased snoring.
- Allergic reactions such as itching, rash or hives. If you experience any of these side effects notify your doctor immediately or seek emergency medical attention.
- Redness and itching may appear at the injection site. If this appears to be particularly troublesome or if the injection area becomes painful, you should discuss this with your doctor.
- Nausea, vomiting, headache, or visual changes. If you experience any of these side effects notify your doctor.
- Swelling, muscle pain or weakness, joint pain, and joint disorders. Notify your doctor if you experience any of these side effects. The most common side-effects of therapy with NUTROPIN AQ for adult GH deficiency were dose-related and include swelling and pain. These side effects tend to improve or disappear with adjustment of the dosage of NUTROPIN AQ.
- If your child shows an unexplained limp, or complaints of hip/kneepain notify your doctor.

This is not a complete list of side effects. For any unexpected

effects while taking NUTROPIN AQ, contact your doctor or pharmacist.

HOW TO STORE IT

NUTROPIN AQ NuSpin must be refrigerated.

NUTROPIN AQ NuSpin should be discarded after 28 days of the first use. Do not store the NUTROPIN AQ NuSpin with needle attached.

When not in use, store under refrigeration at 2-8°C in a dark place.

The NUTROPIN AQ NuSpin **must not be frozen. Protect from light.**

If you have any questions, contact your doctor, nurse or pharmacist.

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Mississauga, Ontario L5N 5M8

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: **Canada Vigilance Program**
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of the side effect, please contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at <http://www.rochecanada.com>.

This leaflet was prepared by Hoffmann-La Roche Limited.

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