



UNDERSTANDING GROWTH IN KIDNEY DISEASE

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

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

Nutropin[®]
[somatropin (rDNA origin) for injection]

UNDERSTANDING KIDNEY DISEASE

If someone in your family has chronic kidney disease (CKD) you probably have many questions. The most basic being: What is it?

The major difference between those who have CKD and those who don't is the degree to which their kidneys function. Normal kidneys keep the body's chemicals in balance and filter blood, to help control blood pressure and tell the body when to make new red blood cells.

Having CKD keeps kidneys from being 100% effective, but they still do some of their normal work.

One of the many stages of CKD is the development of chronic renal insufficiency (CRI), which is sometimes also called CKD.

Kidneys have many jobs in the body. So having CRI can change the way the whole body works.

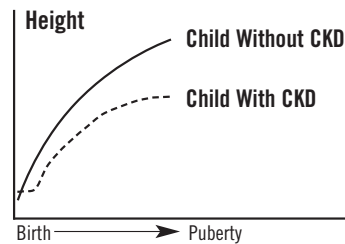
This guide will focus on just one of the important changes — growth failure. CRI makes it difficult to attain a normal height and weight for several reasons (eg, slow bone growth, malnutrition, and problems using protein).¹ This guide will provide information on treating CRI-related growth failure with growth hormone (GH). GH may help some children with CRI grow more normally, especially when started early in life.

GROWTH AND KIDNEY DISEASE

The main reason CRI patients have trouble reaching normal growth or weight is the lack of, or inability to use, GH properly.¹

Even though growth failure is a serious issue for children with CRI, it can be treated with GH therapy. The first two years of life are the time of greatest growth in all children.² However, children who are born with CKD, or develop it in the first few years of life, are likely to grow poorly. Once they have begun to follow a deficient growth pattern, they tend to stay in that pattern and do not catch up to others in their age group unless they are properly treated.

It is important for patients with CRI to maximize their nutritional intake in addition to following the full treatment plan their healthcare team may prescribe.



Adapted from Betts PR, Magrath G. *Br Med J.* 1974;1:189-193.

**The kidneys have many jobs in the body.
Therefore, CRI can change the way the
whole body works.**

Your healthcare provider is your primary source of information.

Please see pages 10-11 for important safety information.

THE ROLE OF GROWTH HORMONE

GH is responsible for telling the body how and when to grow. It also plays a role in how food is used, and in determining bone strength.

GH is made in the pituitary gland, which is at the base of the brain. Many healthcare professionals and scientists call the pituitary the “master gland” because it makes several hormones that activate many other hormones in the body.

When exercising or eating, messages reach the pituitary and tell it to release GH, causing GH levels to change throughout the day. The greatest amount of GH is released while sleeping.

In the past, most young people with CRI grew up to be much shorter than other children. Now scientists can manufacture GH, identical to what the body makes, to help stimulate growth.

When the pituitary gland secretes GH, it normally goes to the liver, where it produces insulin-like growth factors (IGFs).

Think of IGFs as building blocks for growth. While GH does a few things by itself, most of the work is done by IGFs that circulate through the body.

In children with CRI, not all of these things happen the way they should.

Most young people with CRI have normal GH levels, but they don't always grow as well as other people their age because their bodies aren't able to use the GH fully.

HOW GROWTH HORMONE MAKES YOU GROW

GH plays many roles, including making bones grow. This depends on many things, like the food your child eats and the way their body responds to GH. GH also tells the body how and when to make new proteins, which helps keep hair, skin, muscles, and internal organs healthy.

Having CRI means your child may need extra help growing. GH therapy can help kids with CRI to reach a greater adult height.³

TREATING GROWTH FAILURE WITH GROWTH HORMONE

When your child was diagnosed with CRI, their healthcare team began to monitor his/her height and weight more closely, and may even have prescribed GH therapy. The reason they did this was to help your child reach full adult height, which is largely determined by how much they grow now. But before you start, be sure to discuss with your child's healthcare team both the benefits and risks of GH therapy.

GH is given by injection, which is not difficult for most kids to learn or get used to. By age 10, most can give themselves their own injection, after they've had instruction from their healthcare team.

It's also important with CRI to get adequate nutrition, since GH can't make up for malnutrition.

If necessary, check with a nutritionist to make sure your child eats the right foods and continues to take medications as prescribed.

Beginning GH treatment as early as possible will give your child the best chance of reaching a height that is close to normal.³

It is also important to have regular check-ups for a type of bone disease called renal osteodystrophy.

*Your healthcare provider is your primary source of information.
Please see pages 10-11 for important safety information.*

USING NUTROPIN AQ AND NUTROPIN TO TREAT CHRONIC RENAL INSUFFICIENCY GROWTH ISSUES

Nutropin AQ and Nutropin are two types of GH available from Genentech. These two products are indicated for the treatment of growth failure associated with CRI, up to the time of kidney transplantation. Nutropin therapy is one part of the overall strategy to manage your child's CRI in the best possible way.

Genentech's Nutropin AQ Pen® is simple to prepare and use. It is important to follow your healthcare team's instructions. They will tell you how much GH your child should take, and give you proper injection instructions.

If a kidney transplant is being considered, you and your child's healthcare team will try to optimize your child's growth beforehand.

It may take three to six months for Nutropin AQ and Nutropin to have a noticeable effect, so it's important to keep appointments with your healthcare team so changes in your child's body can be monitored. After a few visits, it will be possible to see whether your child grows more quickly than before.

Genentech's Nutropin AQ Pen is simple to prepare and use.

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



There is a lot of information available that indicates GH can help your child grow. Research has shown that patients on Nutropin AQ and Nutropin showed substantial growth in the first and second years of therapy.⁴

Your healthcare provider is your primary source of information. Please see pages 10-11 for important safety information.

NUTROPIN AQ AND NUTROPIN

INDICATION

Nutropin AQ and Nutropin are indicated for the treatment of growth failure associated with CRI, up to the time of kidney transplantation.

IMPORTANT SAFETY INFORMATION^{5,6}

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

If your child is treated at the hospital for any reason, notify your child's healthcare professional, including your child's pediatric nephrologist, 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 your child's doctor if allergic reactions occur, such as itching, rash or 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 your child complains of headache, visual changes, nausea, and/or vomiting, notify your child's healthcare professional immediately.

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

It is important for your child to follow the full treatment plan for their kidney disease including the prescribed special diet.

It is also important to have regular check-ups for a type of bone disease called renal osteodystrophy.

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

Discuss all medications your child is taking with your child's doctor, particularly corticosteroids (like prednisone or hydrocortisone), sex steroids (like estrogens or testosterone), seizure medication or cyclosporine.

ANSWERS TO SOME FREQUENTLY ASKED QUESTIONS

Q: Why must GH be given by injection?

A: GH medications must be given by injection because they are proteins. If the medication were taken by mouth, it would be broken down by digestion in the stomach and intestines and would never get to the rest of the body to do its job.

Q: How will my child know how to use GH?

A: Your healthcare team will teach your child how to administer GH.

Q: How does the healthcare professional decide what dose of GH to prescribe?

A: Your healthcare professional will calculate your child's individualized GH dose based on weight.

Q: Can my child take GH on vacation?

A: Unless your healthcare professional tells you otherwise, continue to administer injections while away from home. Supplies can be carried in a travel cooler. Vials of GH should be kept cold (never frozen) and protected from light. Check with your travel agent or airline to find out about any rules that might affect the transport of medication and injection supplies on board a plane or into another country.

Q: What are the risks of GH therapy in CRI?

A: A small number of patients treated with GH have experienced pressure within the head (combined with visual changes, headache, nausea, and/or vomiting). Patients with growth failure in CRI should have periodic check-ups for a type of bone disease called renal osteodystrophy. Additionally, some patients have experienced hip and/or knee pain, and others have experienced allergic reactions. Contact your healthcare team immediately if you encounter these side effects and to find out about any other risks associated with GH therapy.

Q: How can I monitor therapy?

A: Visit your healthcare team often and follow their directions carefully. To make sure your CRI is being managed in the best way possible, your healthcare team will run tests to see if your child's body is responding to GH therapy.

CRI/KIDNEY PATIENT RESOURCES

www.magicfoundation.org
(MAGIC Foundation)

Offers kids programs such as MAGIC Maniacs Newsletter, a pen pal sign-up list, and a place for kids to share stories.

www.kidney.org
(National Kidney Foundation)

A great source for patient and family education materials.

www.aakp.org
(American Association of Kidney Patients)

Features up-to-date articles, newsletters, and an “Ask the Doctor” section with advice from nephrologists.

The Web sites listed above offer some valuable information, however they are not affiliated with Genentech, Inc. and are not the only sources of information on this topic.

REIMBURSEMENT INFORMATION RESOURCE



With SPOC, Genentech offers:

- Help for individuals and families seeking insurance reimbursement for GH therapy
- A dedicated case management team to assist patients with benefits investigations, claims paperwork, recertification, appeals, and identification of alternative sources of financial support for GH therapy
- Convenient service with a single, toll-free phone call at 1-800-545-0498 or on the Web at www.SPOCOnline.com

*Your healthcare provider is your primary source of information.
Please see pages 10-11 for important safety information.*

References:

1. Warady BA. Growth retardation in children with chronic renal insufficiency. *J Am Soc Nephrol.* 1998;9(12 suppl):S85-S89.
2. National Center for Health Statistics. *Monthly Vital Statistics.* 1976;25(3suppl) [HBA]:76-1120.
3. Fine RN, Kohaut E, Brown D, Kuntze J, Attie KM. Long-term treatment of growth retarded children with chronic renal insufficiency, with recombinant human growth hormone. *Kidney Int.* 1996;49:781-785.
4. Fine RN, Kohaut EC, Brown D, Perlman AJ. Growth after recombinant human growth hormone treatment in children with chronic renal failure: report of a multicenter double-blind placebo controlled study. *J Pediatr.* 1994;124:374-382.
5. Nutropin AQ® [somatotropin (rDNA origin) injection] [package insert]. So. San Francisco, CA: Genentech, Inc.; 2005.
6. Nutropin® [somatotropin (rDNA origin) for injection] [package insert]. So. San Francisco, CA: Genentech, Inc.; 2005.

Nutropin AQ Pen[®] 10
for use with **Nutropin AQ Pen 10 mg Cartridge**
[somatotropin (rDNA origin) injection]

Nutropin AQ[®]
[somatotropin (rDNA origin) injection]

Nutropin[®]
[somatotropin (rDNA origin) for injection]

Your healthcare provider is your primary source of information.

Please see pages 10-11 for important safety information.

Genentech
IN BUSINESS FOR LIFE

For more information, visit us at **Nutropin.com** or
call **1-866-NUTROPIN (1-866-688-7674)**.