

Growth Hormone Deficiency (GHD)

"What may help my child grow?"

"What is GHD?"

"What causes GHD?"

"How can GHD be treated?"

Your questions answered.

ZOMACTON™ [somatropin (rDNA origin)] for Injection **for Pediatric Growth Hormone Deficiency**

Indication:

ZOMACTON™ [somatropin (rDNA origin)] for Injection is a prescription growth hormone product for the treatment of growth failure in children who do not make enough growth hormone on their own. This condition is called growth hormone deficiency.

Select Important Safety Information

ZOMACTON™ is contraindicated in patients with a known sensitivity to benzyl alcohol and metacresol, patients with closed epiphyses, diabetic retinopathy, active malignancy, acute critical illness, and Prader-Willi syndrome.

The following adverse reactions have been observed: headaches (children and adults), gynecomastia (children), and pancreatitis (children and adults).

Please see other Important Safety Information continued on pages 14-16 of this brochure and enclosed Prescribing Information.

ZOMACTON™
[somatropin (rDNA origin)] for Injection
5mg and 10mg

Understanding Growth Hormone Deficiency

A diagnosis of growth hormone deficiency (GHD) can come with so many questions for you and your child. But it's also an answer. And once you understand more about GHD, its causes, and how you can treat it, you can begin to feel more confident that you're armed with the knowledge, treatment, and support you need to help your child on the journey to growth.



"How does a body grow?"

The Endocrine System, Glands, and Hormones

To help you understand the growth process, here is a simple description of what goes on inside a child's body to make it grow.

Growth (along with many other functions) is controlled by the endocrine system. The endocrine system is a network of glands and organs that communicate with each other—and with the rest of the body—by releasing chemicals called hormones.¹

The pituitary gland is a pea-sized organ near the base of the brain. It is often called the "master gland" because it produces many other hormones that control various processes in your body. The pituitary gland produces growth hormone (GH).^{1,2}

GH plays an important role in the body, especially in developing children. It's key to normal growth and metabolism.³

How GH Affects Growth

GH triggers the release of insulin-like growth factor-1 (IGF-1). This hormone circulates throughout the body and causes cartilage cells to grow, which results in bone growth. It also promotes the growth of muscle and other tissues.³

How GH Affects Metabolism

Metabolism is the body's natural process of converting food into energy and waste products. GH affects this process in several ways. It encourages your body to use more amino acids, which creates more proteins. It helps maintain proper levels of carbohydrates in the body and stimulates the use of fat (stored energy) by breaking down triglycerides.³

“Why do some bodies not grow properly?”

Defining Growth Hormone Deficiency



Simply put, a child with GHD is not producing enough growth hormones for normal development. GHD is a condition that affects both boys and girls. In fact, there are an estimated 1 in 4,000 to 10,000 children who have GHD.⁴

GHD may occur by itself or in combination with other hormone deficiencies. And there are different degrees of GHD. **Total GHD** means that no growth hormone is produced at all. If some growth hormone is produced, but not enough for normal growth, it is called **partial GHD**.⁵

In many cases, no cause for GHD can be found. Researchers continue to try to learn more, and they have been able to divide GHD into 2 groups: **congenital GHD** and **acquired GHD**.⁵



Congenital GHD

“Congenital GHD” means that the child has been born with this condition. From birth, the endocrine system doesn’t work properly to encourage normal growth. This *may* be the result of something that happened while the child was in the womb, such as an injury or other complication, but the cause can’t be known for sure. Congenital GHD may not be noticeable for months or even years after the child is born.⁵

Acquired GHD

Damage to the pituitary gland or other important parts of the endocrine system after birth can result in “acquired GHD.” Serious illness, exposure to radiation therapy or a head injury can result in GHD at any time during infancy or childhood. Often, a tumor affecting the hypothalamus or pituitary gland will cause acquired GHD. But even if the tumor is removed, it may not correct the degree of GHD.⁵

Other Impacts on Growth

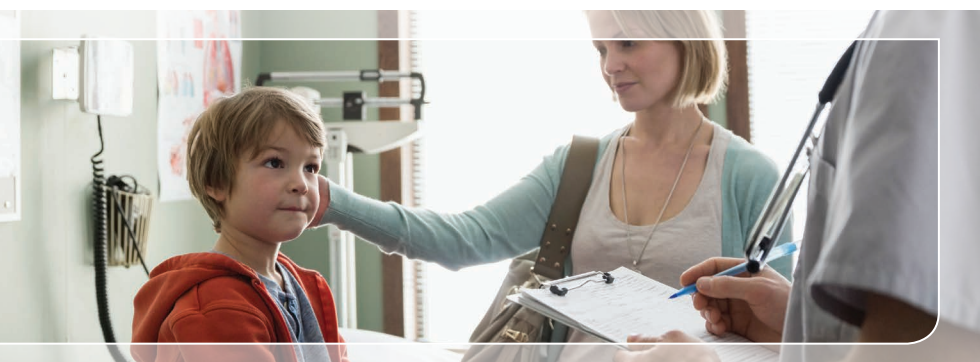
There are other factors besides GHD that may impact a child’s growth. Poor nutrition, more than anything, may prevent a child from growing at a normal rate. A balanced diet is essential to the healthy development of growing children. However, even if a child eats a balanced diet, growth problems can still occur if the food is not absorbed and metabolized properly.^{5,6}

Discovering Treatment Options

Remember: Although in many cases no cause can be found for GHD, now you can get help—by working with your doctor to get the proper treatment and support.

“How can growth hormone replacement therapy help?”

Your Doctor Has Recommended Growth Hormone Replacement Therapy



You and your doctor have decided to treat your child's GHD with ZOMACTON™ [somatropin (rDNA origin)] for Injection. ZOMACTON™ is a prescription growth hormone product for the treatment of growth failure in children who do not make enough growth hormone on their own. This condition is called growth hormone deficiency, or GHD.

ZOMACTON™ has been approved by local health authorities outside of the United States to treat GHD since 1988 in 47 countries around the world.^{3,4}

With human growth hormone (hGH) therapy like ZOMACTON™, your child may reach a height similar to that of other children his or her age. Not everyone responds to hGH therapy in the same way. However, today most children receiving replacement therapy reach a normal adult height consistent with the average height of others in their family. The sooner your child begins treatment, the more successful therapy is likely to be.^{4,5}



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Beginning GH Therapy

GH therapy with ZOMACTON™ only works when injected. If ZOMACTON™ was taken by mouth, it would be broken down in the stomach and digested. Then it would not work properly. So, yes, your doctor will prescribe injections for your child, based on weight, that will have to be given three (3) times a week.

The recommended dosage of up to 0.1 mg/kg of body weight administered subcutaneously (under the skin/injected) three (3) times per week (up to 0.3 mg/kg/week). **For complete dosing information please refer to the Instructions for Use section of the ZOMACTON™ Prescribing Information.**

Injection Options

ZOMACTON™ is available in 5-mg and 10-mg vials. Your doctor will decide whether 5 mg or 10 mg will be best for your child.

Select Important Safety Information

WHO SHOULD NOT TAKE ZOMACTON™?

- Benzyl alcohol, a component used to reconstitute the ZOMACTON™ 5-mg vial, should not be used with newborns. Benzyl alcohol has been associated with serious adverse events and death. When administering ZOMACTON™ 5 mg to newborns, it should be reconstituted with sterile normal saline. Benzyl alcohol should not be used in patients with a known sensitivity.

Please see other Important Safety Information continued on pages 14-16 of this brochure and enclosed Prescribing Information.

“What if I have questions about treatment or insurance?”

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The ZoGo Support Program Can Help



When you choose ZOMACTON™ [somatropin (rDNA origin)] for Injection, you're not only getting a GH therapy with an established track record, but you're also getting all the support you need throughout treatment with ZoGo, your personalized support program.



Your doctor's office staff will enroll eligible patients in the ZoGo Support Program and let the ZoGo team know your child is being prescribed ZOMACTON™. Our team of professionals is with you every step of the way, 24 hours a day, seven days a week. Patients must meet eligibility requirements to access certain Program benefits. Please contact the ZoGo Support program at 844-944-ZOGO (9646). You'll get a welcome phone call to answer any immediate questions and a complete Welcome Kit with tools and information about GH therapy and ZOMACTON™. In addition, one of our specially trained nurses will come to your home to teach you and/or your caregiver how to safely and correctly give your child ZOMACTON™ injections.

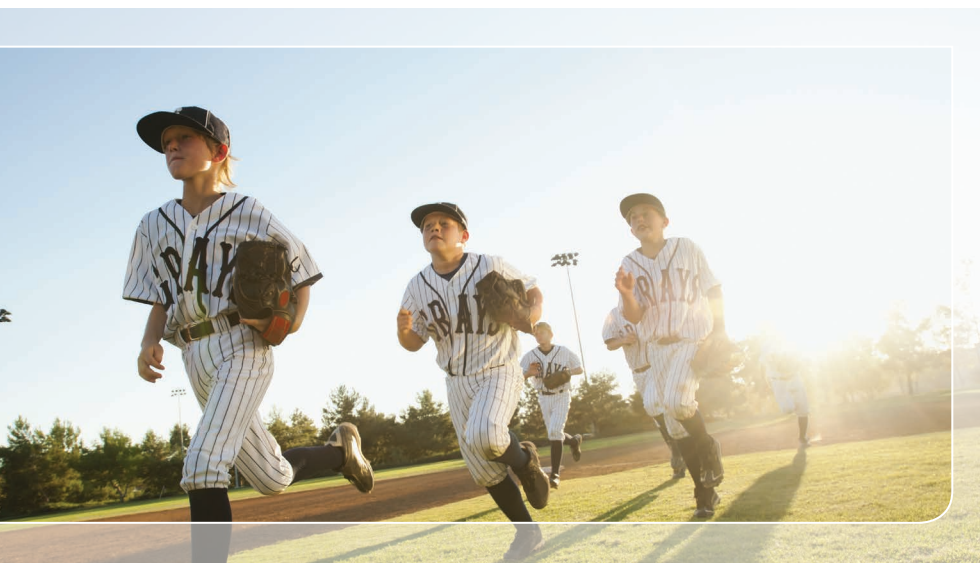
But it doesn't stop there. The ZoGo Support Program team will help make sure your shipment of ZOMACTON™ is received and even coordinate insurance coverage with your pharmacy. There are also special ZOMACTON™ financial assistance programs that you may qualify for as well. The ZoGo Support Program team can help you with that, too.

Throughout treatment, the ZoGo Support Program team will continue to be your contact for information, insurance coverage, and refills. Thanks to ZoGo, with ZOMACTON™ treatment you'll never have to go it alone.

Please see other Important Safety Information continued on pages 14-16 of this brochure and enclosed Prescribing Information.

“What should we expect from GH therapy?”

Treatment and Progress With ZOMACTON™ [somatropin (rDNA origin)] for Injection



Your physician will monitor your child's response to ZOMACTON™. It's possible your child may experience side effects; if he or she does experience any side effects, you should talk to your doctor immediately. We've included Important Safety Information on pages 14-16 of this brochure. You can also refer to the enclosed Prescribing Information.



The First Few Months

As you begin treatment, there is sometimes a sudden “spurt” in growth rate. This fast increase may be noticeable to you and your child within 3 to 4 months. Eventually, growth will progress more slowly, but remain steady. During this initial period of treatment, you may notice an increase in your child's appetite and a loss of body fat.⁵

Stay the Course

If this sudden growth spurt doesn't occur, or once it has tapered off, you and your child may become impatient and expect faster results. Don't become discouraged or give up. Stay on track. Stick to the plan and dosing schedule provided by your doctor. Always take ZOMACTON™ exactly how your doctor has prescribed it and **NEVER** increase the dose or number of injections per week.

Be Positive

You will likely see results over time. But, remember that growth is a slow process measured over many months and possibly years. If your child expects to grow suddenly overnight after starting treatment, he or she will be disappointed. Your doctor will discuss realistic short- and long-term expectations with you and will determine how long you will remain on GH. Treatment may last into the late teens or early adulthood. It's important that you explain all this to your child, and remind your child (and yourself) to be patient.⁵ Good communication during this journey is crucial to help your child to keep a positive outlook.⁵

Please see other Important Safety Information continued on pages 14-16 of this brochure and enclosed Prescribing Information.

“How can I help my child throughout treatment?”

Positive Support for Children With GHD



Remember, smaller doesn't mean younger. And just because your child is small in size doesn't mean he or she should be treated as if he or she were younger. For children with GHD to mature and grow emotionally, they need to be treated like children their own age. This can sometimes be hard for other children and even adults may treat a small child as if he or she was younger. It's important for you to talk to your child about this. Provide encouragement, praise any accomplishments, and boost their confidence whenever you can. It's also important to talk to your child's teachers and classmates. Help them understand a little bit about GHD and ask for their help in keeping your child positive.



Getting the Results

Treatment for children with GHD is a journey. It's not always easy for them, or for you. But if you and your child can keep a positive attitude, and stick with **ZOMACTON™ [somatropin (rDNA origin)] for Injection**, the results can be satisfying. For more information, visit zomacton.com or call 1-844-944-ZOGO (9646).

Please see other Important Safety Information continued on pages 14-16 of this brochure and enclosed Prescribing Information.

References

1. The Hormone Health Network. Hormones and health; an introduction to the endocrine system. <http://www.hormone.org/endo101/>. Accessed March 15, 2015.
2. KidsHealth from Nemours. Endocrine system. http://kidshealth.org/parent/general/body_basics/endocrine.html#. Accessed March 15, 2015.
3. Bowen RA. The hypothalamus and pituitary gland: introduction and index. In: Bowen RA, Austgen L, Rouge M, eds. *Pathophysiology of the Endocrine System*. <http://www.vivo.colostate.edu/hbooks/pathphys/endocrine/index.html>. Updated April 30, 2006. Accessed March 15, 2015.
4. Boston Children's Hospital. Growth hormone deficiency in children. <http://www.childrenshospital.org/conditions-and-treatments/conditions/growth-hormone-deficiency>. Accessed March 15, 2015.
5. Rieser PA. Pediatric growth hormone deficiency. In: Owens RP, Root AW. *Growth Hormone Deficiency*. The Human Growth Hormone Foundation booklet; 1979.
6. The Magic Foundation. What causes children to grow poorly? <https://www.magicfoundation.org/www/1237>. Updated December 12, 2007. Accessed March 15, 2015.

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PATIENT IMPORTANT SAFETY INFORMATION

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Important Safety Information

WHO SHOULD NOT TAKE ZOMACTON™?

- Benzyl alcohol, a component used to reconstitute the ZOMACTON™ 5-mg vial, should not be used with newborns. Benzyl alcohol has been associated with serious adverse events and death. When administering ZOMACTON™ 5 mg to newborns, it should be reconstituted with sterile normal saline. Benzyl alcohol should not be used in patients with a known sensitivity.
- You should not take ZOMACTON™ if you are allergic to any of the ingredients in the medicine. ZOMACTON™ 10-mg vial is reconstituted with bacteriostatic water for injection containing metacresol; therefore, ZOMACTON™ should not be used by patients allergic to metacresol.
- ZOMACTON™ should not be used in children whose growth plates in their bones have closed (closed epiphyses).
- ZOMACTON™ should not be used in diabetic patients with certain types of eye problems (diabetic retinopathy).
- ZOMACTON™ should not be used if you have active cancer. Because growth hormone deficiency can be an early sign of some tumors in the brain or pituitary gland, the presence of these types of tumors should be ruled out by your doctor before you start ZOMACTON™.
- You should not take ZOMACTON™ if you are having serious complications after undergoing open heart surgery, abdominal surgery, serious injuries involving many body systems, or life-threatening breathing problems. Deaths have been reported in such cases.
- Growth hormone should not be used in children with Prader-Willi syndrome who are severely obese or have a history of severe breathing problems. Deaths have been reported in children with Prader-Willi syndrome who are severely obese or who have a history of blocked upper airways, sleep apnea (pauses in breathing during sleeping), or other severe breathing problems. ZOMACTON™ has not been approved for the treatment of pediatric patients with Prader-Willi syndrome.

WHAT SHOULD I TELL MY DOCTOR BEFORE OR WHILE TAKING ZOMACTON™?

- Tell your doctor if you have Prader-Willi syndrome. There have been reports of death in children with Prader-Willi syndrome who recently started growth hormone therapy and had one or more of the following risk factors: obesity, history of severe breathing problems or sleep apnea (pauses in breathing during sleeping), or unidentified respiratory infection. Boys with one or more of these risk factors may be at greater risk than girls. A child with Prader-Willi syndrome should be evaluated by a doctor for signs of severe breathing problems or sleep apnea before starting growth hormone therapy.
- Tell your doctor if you have a history of pancreatitis before taking ZOMACTON™. Cases of pancreatitis (inflammation of the pancreas) have been reported rarely in children and adults receiving growth hormone. Consult a doctor if you develop abdominal pain while taking ZOMACTON™.

- In childhood cancer survivors, treatment with growth hormone may increase the risk of developing a new tumor, in particular certain brain tumors. If you had cancer as a child and received radiation treatment to your head, you may have a greater risk of developing a new tumor if you are treated with growth hormone. The most common type of tumor reported in people treated with growth hormone after radiation to the head was a tumor of the covering of the brain, called a meningioma. If you developed growth hormone deficiency because you had a tumor inside the head or received radiation to the head, you should be monitored closely by your doctor during treatment with growth hormone. Children who have some rare genetic conditions may have a greater risk of developing a tumor if treated with growth hormone. If you have moles/beauty marks on your skin you should have these checked carefully for any changes while being treated with growth hormone.
- Your doctor should check your blood sugar regularly while you are taking ZOMACTON™, especially if you have risk factors for diabetes. If you have diabetes or impaired glucose tolerance, your doctor should monitor your blood sugar closely during ZOMACTON™ therapy. New cases of type 2 diabetes have been reported in patients taking ZOMACTON™.
- If you have low pituitary hormone production levels and are on standard hormone replacement therapy, your doctor should monitor your hormone replacement therapy closely while taking ZOMACTON™. You should have your thyroid function tested periodically during ZOMACTON™ therapy. Thyroid hormone treatment may need to be started or adjusted.
- Slipped capital femoral epiphysis (fracture in the ball of the hip joint) can occur in children who have endocrine problems and in children who have rapid growth. Any child taking ZOMACTON™ who develops a limp or complains of hip or knee pain should be seen by a doctor to check for slipped capital femoral epiphysis.
- Tell your doctor if you have any visual changes accompanied by headache, nausea, and/or vomiting while taking ZOMACTON™. This may be a sign of increased pressure in the brain.
- Progression of scoliosis (curvature of the spine) can occur in children who have rapid growth.
- You should rotate your injection sites to avoid breakdown of skin and fat. Seek prompt medical attention for any allergic reaction you experience to the injection of ZOMACTON™.
- ZOMACTON™ may affect how other medicines work, and other medicines may affect how ZOMACTON™ works, so be sure to tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take: glucocorticoid medication, thyroid hormone, insulin or other medicine for diabetes, medicines that are metabolized by the liver (e.g., corticosteroids, sex steroids, anticonvulsants, cyclosporine), or oral estrogen replacement medicine.
- If you are pregnant or nursing, you should talk to your doctor before using ZOMACTON™. It is not known whether ZOMACTON™ is excreted in human milk. ZOMACTON™ should be used during pregnancy only when clearly needed.

Important Safety Information continued on the next page.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF ZOMACTON™?

- Common side effects reported in adults and children taking ZOMACTON™ include headaches, enlarged breast tissue (gynecomastia), and inflammation of the pancreas (pancreatitis). Other side effects might include injection site reactions (such as pain, numbness, redness, and swelling), allergic reactions to the product or any of its ingredients, and low levels of thyroid hormone (hypothyroidism). Leukemia and new-onset type 2 diabetes mellitus have been reported in patients treated with growth hormone therapy.
- You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 800-FDA-1088.

HOW SHOULD I STORE ZOMACTON™?

- Before reconstitution, vials of ZOMACTON™ are stable when refrigerated at 36° to 46°F (2°C-8°C). Avoid freezing the accompanying diluent. Expiration dates are stated on the labels. After reconstitution, ZOMACTON™ 5 mg is stable for up to 14 days when reconstituted with bacteriostatic 0.9% sodium chloride (normal saline), USP, and stored in a refrigerator at 36° to 46°F (2°C-8°C). Do not freeze the reconstituted solution. ZOMACTON™ 10 mg is stable for up to 28 days when reconstituted with 1-mL syringe of bacteriostatic water for injection containing 0.33% metacresol as a preservative, and stored in a refrigerator at 36° to 46°F (2°C-8°C). Do not freeze the reconstituted solution.

Please see accompanying Full Prescribing Information for ZOMACTON™.



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The individuals depicted are models, not actual patients.

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