What is Growth Hormone (GH)?
GH is not a steroid. GH is a natural protein hormone (made up of amino acids) secreted by the pituitary gland. GH therapy uses a synthetic form of human growth hormone with the same chemical structure as naturally made GH. It is made using recombinant DNA technology.

What are the GH Products in Canada?
There are various brands of GH available in Canada. There are some differences in cost of the medication between companies. Health Canada has approved all of these GH products for use in children. In Ontario we are permitted to use (in alphabetical order):

<table>
<thead>
<tr>
<th>GH</th>
<th>Pharmaceutical Company</th>
<th>Websites for GH product and device information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotropin</td>
<td>Pfizer Canada</td>
<td><a href="http://www.genotropin.ca">www.genotropin.ca</a></td>
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<tr>
<td>Humatrope</td>
<td>Eli Lilly Canada</td>
<td><a href="http://www.humatrope.com">www.humatrope.com</a></td>
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<tr>
<td>Norditropin</td>
<td>Novo Nordisk</td>
<td><a href="http://www.norditropin.com">www.norditropin.com</a></td>
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<tr>
<td>Omnitrope</td>
<td>Sandoz Canada</td>
<td><a href="http://www.omnitrope.com">www.omnitrope.com</a></td>
</tr>
<tr>
<td>Saizen</td>
<td>EMD-Serono</td>
<td><a href="http://www.easypod.ca">www.easypod.ca</a></td>
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</tbody>
</table>

Why is GH necessary?
It is indicated as a treatment in children with GH deficiency. GH may also be used to help growth in other conditions:
1) Children with chronic diseases/syndromes that impact growth.
2) Idiopathic Short Stature/Small for gestational age.

For those with GH deficiency, how is it diagnosed?
GH deficiency is diagnosed through growth hormone stimulation testing and assessment of growth rate.

How is the best GH dose for each child determined?
Various dosage ranges depend on:
1) Diagnosis
2) Literature recommendations (Generally: 0.03 mg/kg/dose -0.05mg/kg/dose)
3) Goals of and response to treatment
4) Blood tests: including IGF-1 level
5) Body weight

How is GH given?
As GH is a protein, it can be digested in the stomach, and will not work if taken by mouth. It must be given by subcutaneous (under the skin) injection.

Where are the subcutaneous injections given?
GH is given into the arms, legs, buttocks or abdomen. Injections are rotated between these sites.

December 2020
How often are injections given?
Injections are given 6 times per week. Missed injections may be given on the 7th day. *GH therapy requires long-term commitment by children and their families.*

When are GH injections given?
GH injections can be given any time of day. However, it is generally recommended to be given in the evening prior to bed as children normally make more GH at night.

How much growth can we expect?
Generally, prior to GH therapy growth is less than 5 cm/year. During the first year of GH therapy growth may reach up to 8-10 cm and then usual growth is expected (approximately 5 cm+ per year) following the first year.

How often will we need to be seen in Clinic for follow up?
Every 4 - 6 months during the initial year of GH therapy. During puberty, adolescents may be seen every 4 months.

What can I expect at these clinic visits?
- Assessment of height and weight.
- Review of health and side effects.
- Physical assessment (general).
- Bone age x-rays (periodically).
- Blood testing (approx. once per year).
- New dose and prescription of GH based on new weight and response to treatment.

How long will my child be on GH?
1) Until full growth has been largely attained (as measured by very little recent growth) and a bone age x-ray showing near closure of growth plates and a bone age of 14-16 years.
2) You and your child no longer wish to continue with therapy.
3) Sometimes, children do not respond and we consider stopping GH therapy for this reason.
4) Some young adults may require continuation of GH therapy into adulthood. Repeat testing for adult GH deficiency may be required to determine if GH deficiency persists into adulthood.

What effects may we expect while my child is on GH?
- Increased height
- Increased weight
- Increased muscle mass
- Increased bone mass
- Increased strength

You may also notice:
- Reduction of adipose (fat) tissue
- Increased metabolism,
- increased appetite
What are the Side Effects of GH Therapy (GH treatment)?
GH is one of the most studied drugs/hormones in medicine. To date thousands of research studies/articles have been published on the use of GH. It has a very safe drug profile. Synthetic GH has been used in Canada since 1986. There are no known drug interactions and routine immunizations may be given. Side effects of GH therapy are very rare. However, in theory there are some potential risks which will be monitored for at your child’s follow-up visits.

Headache: Benign Intracranial Hypertension (BIH) or (pseudotumour cerebri).
BIH is reported to occur in 1:1000 children receiving GH. It is not clear why it occurs. Theory suggests that retention of salt and water that can occur at the beginning of GH treatment may cause increased pressure within the fluid that circulates around the brain and children will complain of or experience headache, nausea or vomiting. It may occur within the first months of GH treatment and will resolve rapidly when GH is stopped and restarted at a lower dose and increased slowly over time (usually without further problems).
Typically, the child will awaken with a headache 1 to 2 days in a row (with or without nausea and vomiting) that will not improve with administration of Tylenol® or Advil ®.

Slipped Capital Femoral Epiphysis (SCFE)
SCFE occurs when the growing part of bone (epiphysis) at the top of the thigh bone (femur) slips out of alignment. This may occur in children who are growing quickly or are overweight or who have GHD after treatment for leukemia or brain tumours. Symptoms of SCFE are hip/knee pain or limping. SCFE is not caused directly by GH treatment but is related to the rapid growth spurt that can occur after starting.

Scoliosis
In children with scoliosis (abnormal curve of the spine) the degree of curvature may worsen when growth accelerates with the use of GH. Your child’s spine will be assessed regularly.

Risk of Cancer
GH stimulates the growth of cells however studies have not shown increased rate of cancers in children treated with GH. During GH treatment, we monitor levels of IGF-1 and make adjustments to keep this in the normal range. Some studies have associated very high levels of IGF-1 with tumour formation, although it is unclear whether this is the cause, or purely coincidence. The use of GH in cancer survivors is not associated with increased risk of recurrence of the initial cancer, or of death.

Risk of Diabetes
One of the functions of GH naturally is to increase the amount of sugar in the blood in times of stress. It does this by decreasing the body’s sensitivity to insulin (a hormone that helps transport sugar from blood into cells in the body). Reduced sensitivity to insulin may lead to the development of Type 2 Diabetes. Most studies do not show an increased incidence of Type 1 or 2 Diabetes associated with GH treatment. However, factors that may increase the risk include children taking high dose glucocorticoids and those that are overweight or have a parent with diabetes. Symptoms of diabetes include increased thirst and urination.
Risk of Stroke
There has been a recent report (2014) of an increased risk of stroke among adults who had been treated with GH as children. However, the absolute risk (the number of people who developed stroke) was very small, and there are some scientific concerns about how this study was done, which makes it hard to draw firm conclusions. Major professional organizations continue to feel that, for properly selected patients, GH remains a safe and effective treatment.

Other potential side effects:
- Swelling of hands and feet (more frequent in adults).
- Increase in number of moles or nevi (more common in Turner Syndrome)
- Lipoatrophy: loss of fat under the skin surface causing a dip or dimple from repeated injections to the same site.
- Lipohypertrophy: soft grape like lump at the injection site which represents a build up of fat or scar tissue from repeated injections to the same site.

Is there any additional information we need to know about GH therapy?
- GH must be stored in a cool (refrigerated) place at all times. 2 types of GH (Saizen vials and Genotropin MiniQuick) can be stored at room temperature until mixed.
- Use a small cooler with ice pack for travel.
- A new needle/syringe is needed for every injection. Proper disposal in a sharps container is required.
- No need for a medical alert bracelet (unless necessary for other medical conditions or medications).
- Treatment may be continued during illness.

Where do I obtain GH medication?
For those with growth hormone deficiency, GH must be obtained from our SickKids Shoppers Drug Mart pharmacy. For others, GH may be purchased at a local pharmacy.

The SickKids Shoppers Drug Mart Out-Patient Pharmacy:
416-813-6700
Hours of operation: Monday-Thursday 7:30am-7:00pm
Friday 7:30am-7:00pm
Saturday 9:00am-5:00pm
Sunday 11:00am-5:00pm

How do we get started?
Once you have secured funding, if it was required, you will need to advise our Growth Hormone Funding Coordinator of your approval and send a copy of the approval letter to fax # 416-813-8770 or email to lynda.carty@sickkids.ca

Next you will receive an e-mail with information regarding the GH products. You and your child will review the information and decide which GH product will best suit your lifestyle. Once you have decided, you will reach out to our team to provide your decision. An enrollment form will then be sent to the GH company along with a prescription to the appropriate pharmacy. The GH company will then reach out to you to schedule a teaching session. You can expect to be seen for a follow up appointment in the Endocrinology Clinic about 4 months after starting therapy.
Giving Injections to Your Child

Giving your child an injection requires patience. Injections are a routine part of the lives of thousands of children and your child will learn to accept it as a part of his/her routine.

Strategies for Injection: Toddler/Preschooler

Before the injection:
- Establish a consistent routine. Using the same special toy for your child to hold each time, or repeating a favourite song, phrase or story while you give their injection may be helpful.
- Explain what you are about to do.
- Make it clear the medicine is not a punishment for bad behaviour.
- Reinforce that the discomfort will soon be over.
- Let your child help decide what injection site to use (but remember to rotate sites)
- Give injection quickly, delaying will only make your child more anxious and prolong the process.

During the injection:
- When you have to restrain your child explain you are helping him/her to ‘hold still’.
- Teach your child to relax (ie) toe wiggling helps when you are injecting into the thigh or use any distractions available.

After the injection:
- Cuddle and hug your child. Allow your child to play as this relieves tension.

Strategies for Injections: School age

Before the injection:
- Stick to a consistent routine.
- Explain that the injection is “medicine to help you grow”.
- Answer all questions honestly.
- Let your child help select the area in which you’ll inject (remember to rotate sites)

During the injection:
- Let your child take part in the injection process

After the injection:
- Encourage your child to talk about any feelings or anxiety, and remember to praise and reward positive behaviour.

Strategies for Injections: Teenager

Before the injection:
- Establish a routine to provide consistency.
- Answer your child’s questions simply and concisely.

During the injection:
- Let your teen take part in the injection process as much as he or she wants to with your supervision.
- If reconstituting GH, should be done in the presence of an adult.

After the injection:
- Praise and reward your child’s positive behaviour appropriately.
- Respect your teenager’s decisions about whether friends and relatives should or should not know about his or her therapy.