

**PART III: CONSUMER INFORMATION**

**HUMATROPE®**  
**(somatropin for injection)**  
*pronounced HYOO-mah-trope*

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

Please read this information carefully before you start to take your medicine, even if you have just refilled your prescription. Some of the information may have changed. Keep this pamphlet since you may need to refer to it after starting treatment with HUMATROPE.

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

HUMATROPE is used to treat children and teenagers who do not develop to their normal height because of poor bone growth. Growth hormone deficiency, Turner syndrome, idiopathic short stature, SHOX (short stature homeobox-containing gene) deficiency, and born small for gestational age are medical conditions, which result in slow bone growth.

HUMATROPE is also used in some adults who had growth hormone deficiency when they were children or who do not have enough growth hormone as adults for some other reason.

**What it does:**

HUMATROPE is used to increase growth hormone levels. It stimulates bone growth in children unless the ends of the bones have hardened (closed epiphyses). In both adults and children with growth hormone deficiency, it also increases the growth of muscle and reduces body fat.

**When it should not be used:**

Treatment should not be started:

- To promote growth when the ends of the long bones have hardened (closed epiphyses).
- In patients with any evidence of an active cancer (either newly diagnosed or recurrent).
- While patients have a serious illness following surgery, or who have just had a serious accident, or those with acute respiratory failure (low level of oxygen in the blood or high level of the carbon dioxide in the blood)
- In patients with Prader-Willi syndrome, who are very overweight or have severe breathing problems.

**Treatment should not be started:**

- In patients known to be allergic to somatropin, to any of the ingredients in the powder for solution for injection or the diluent.
- In patients who have undergone renal transplant, until one year post-transplant.

**What the medicinal ingredient is:**

Somatropin (recombinant human growth hormone)

**What the important nonmedicinal ingredients are:**

The HUMATROPE powder contains dibasic sodium phosphate, glycine, and mannitol.

The diluent (solution for dissolving somatropin) contains - metacresol and glycerin.

Phosphoric acid and/or sodium hydroxide may have been added at the time of manufacture to adjust the acidity of the liquid.

**What dosage forms it comes in:**

HUMATROPE is supplied as follows:

Vial: 5 mg vial plus 5 mL diluent

Cartridges: 6 mg, 12 mg, or 24 mg cartridges, each with 3.15 mL of diluent.

HUMATROPE cartridges require the use of a HumatroPen to inject the drug. HumatroPens are supplied separately.

**WARNINGS AND PRECAUTIONS**

A doctor trained in hormone disorders must examine the patient to decide if it is safe to use HUMATROPE.

Treatment with growth hormone (GH) can change blood sugar levels.

Following an overdose of HUMATROPE, the patient may feel sick, shaky or light-headed due to low blood sugar. These feelings quickly disappear, but the patient's blood sugar may then rise above normal 2-4 hours after injection. Therefore, the patient's blood sugar should be tested regularly after an overdose.

When medicine is injected into the same place over a long time, it can cause damage. It is therefore important to keep changing the injection site, and the doctor or nurse can tell you how.

Before you use HUMATROPE, the patient or caregiver should tell the doctor:

- if the patient has an active brain tumour or any other tumour (cancer). However, your doctor may prescribe HUMATROPE if the patient has had a brain tumour and needs no more anti-tumour treatment for it. The patient should be re-examined frequently to make sure

- that the tumour has not come back or started to grow.
- if the patient is a survivor of childhood cancer.
- if the patient is very ill after a serious operation, or after being treated for multiple injuries from an accident, or if the patient has sudden serious breathing problems.
- if the patient has diabetes (because more or less insulin may be needed when taking HUMATROPE).
- if a member of the patient's family has diabetes.
- if the patient is taking a steroid (glucocorticoid) hormone such as cortisone or prednisone. This is because the combination may reduce the success of the HUMATROPE or because more of the steroid medication may be needed when the patient is also taking HUMATROPE.
- if the patient is taking a medication known to be metabolized by certain liver enzymes (e.g., cyclosporine, some anticonvulsants, and sex steroids such as estrogen and birth control pills). This is because the treatment with HUMATROPE may reduce the effectiveness of the drugs.
- if the patient, especially a child, develops abdominal pain.
- if the patient is or becomes pregnant or is breast-feeding.
- if the patient has hypothyroidism (low levels of thyroid hormone), because HUMATROPE may reduce the levels of thyroid hormone.
- if the patient suffers from a bad headache or frequent headaches, or from problems with eyesight, vomiting or feeling sick. Very rarely, swelling of the brain may develop, and the doctor may want to examine the patient to look for signs of brain swelling. If this occurs it may be necessary to stop the growth hormone treatment.
- if the patient develops a limp, or has hip or knee pain while being treated with HUMATROPE.

Do not use the diluent (the liquid used to mix with the HUMATROPE powder) if the patient is sensitive or allergic to metacresol or glycerol, which are components of the diluent.

If the patient has Turner syndrome and develops an ear infection or headaches tell your doctor about these problems.

Leukemia has been reported in a small number of pediatric patients who have been treated with growth hormone, including growth hormone of pituitary origin, and man-made growth hormone products such as somatrem and somatropin. The relationship, if any, between leukemia and growth hormone is uncertain.

## INTERACTIONS WITH THIS MEDICATION

Tell the doctor if the patient is taking the following drugs:

- Steroid medications such as glucocorticoids (e.g. cortisone or prednisolone)
- Medications known to be metabolized by certain liver enzymes (e.g., cyclosporine, some anticonvulsants, and sex steroids such as estrogen and birth control pills)

- Insulin and anti-hyperglycemic agents

## PROPER USE OF THIS MEDICATION

Be sure to change the injection site frequently to help prevent lipoatrophy (a loss of tissue under the skin).

In general, HUMATROPE should be injected in the evening or before bedtime.

### Usual dose:

Your doctor will instruct you on what is the best dosage of HUMATROPE for you based on your individual needs. Use HUMATROPE exactly as your doctor tells you to.

### Reconstitution Instructions:

HUMATROPE Vials: Please refer to the instruction leaflet provided in the vial package.

HUMATROPE Cartridges: Please refer to the instruction leaflet provided in the cartridge package.

### Overdose:

Long-term overdosage may result in continued growth of the extremities (fingers, toes, nose, ears, jaw) and joint pain. If you think this is happening to you, tell your doctor.

Overdose may change blood sugar levels, and patients may experience symptoms of hypoglycaemia (low blood sugar), such as feeling shaky, dizzy and unwell or hyperglycemia (high blood sugar), such as increased urination or thirst.

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:

Contact your physician or pharmacist if you have missed a dose.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Some people may be allergic to the diluent (liquid used to mix with the HUMATROPE powder). If there is any pain or redness at the injection site, or if there is any swelling, tell your doctor.

It is also important to have your blood glucose checked if you have diabetes or a family history of diabetes.

Children treated with HUMATROPE may have an increased risk of developing pancreatitis. If your child develops abdominal pain, please contact your doctor.

HUMATROPE may affect the way your body handles sugars from your food and drink. Your doctor may check the amount of sugar in your urine or blood.

HUMATROPE can affect the amount of thyroid hormone in the blood, so patients must have thyroid function tests from time to time. If the thyroid is not working properly, HUMATROPE may not work as well as it should.

Any child who begins to limp must be examined by a doctor.

HUMATROPE may cause intracranial hypertension (increased pressure within the skull). Call the doctor if the patient has: a headache that doesn't go away or is severe, or has headaches that become more frequent; problems with vision; nausea (feeling sick in the stomach) or vomiting.

Other possible side effects include headaches, muscle or joint pains, swelling, tingling sensations, feeling weak, high blood pressure, shortness of breath, and sleep apnea (pauses in breathing during sleep). Rarely the headaches may be bad or frequent, and with sickness or vision problems. Tell your doctor immediately if this happens.

For patients with Turner syndrome, growth hormone therapy may increase the already high frequency of ear infections. Your child should see her doctor if you think she has an ear infection.

***This is not a complete list of side effects. For any unexpected effects while taking HUMATROPE, contact your doctor or pharmacist.***

## HOW TO STORE IT

### **Before reconstituted:**

Store the vials or cartridges and diluent in the refrigerator at 2–8 °C.

### **After reconstituted:**

When the vial or the cartridge is prepared with the supplied diluent, it may be stored in the refrigerator at 2 – 8 °C. Do NOT freeze.

- If prepared from the vial with the supplied diluent, it MUST be used within 21 DAYS
- If prepared from the cartridge with the supplied diluent, it MUST be used within 28 DAYS

When the vial or the cartridge is prepared with Sterile Water for Injection, USP, it should be used immediately. Although not recommended, it may be stored in the refrigerator at 2 – 8 °C, but must be used within 24 HOURS. Do NOT freeze.

Keep out of reach of children.

## 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](http://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 0701D  
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](http://www.healthcanada.gc.ca/medeffect).

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

## MORE INFORMATION

For more information, please contact your healthcare professionals or pharmacist first, or Eli Lilly Canada Inc. at: 1-888-545-5972, or visit the website at: [www.lilly.ca](http://www.lilly.ca)

The information in this document is current as of the last revision date shown below. For the most current information please visit our website or contact us directly.

This leaflet was prepared by Eli Lilly Canada Inc., Toronto, Ontario, M1N 2E8

Last revised: August 24, 2011