PART III: CONSUMER INFORMATION (Lyophilized Powder)

PrOMNITROPE®
AWM nee trope
(Somatropin for Injection)
Lyophilized powder: 5.8 mg/vial

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

ABOUT THIS MEDICATION

What the medication is used for:
In children, Omnitrope is used to treat the following growth problems:

- If you are not growing properly and you do not have enough of your own growth hormone.
- If you have Turner syndrome. Turner syndrome is a chromosomal error in girls that can affect growth - your doctor will have told you if you have this.
- If you were small or too light at birth. Growth hormone may help you grow taller if you have not been able to catch up or maintain normal growth by two years of age or later.
- If you have idiopathic (unknown cause) short stature.

In adults, Omnitrope is used to treat persons with pronounced growth hormone deficiency. This can start during adult life, or it can continue from childhood.

If you have been treated with Omnitrope for growth hormone deficiency during childhood, your growth hormone status will be retested after completion of growth. If severe growth hormone deficiency is confirmed, your doctor will propose continuation of Omnitrope treatment.

What it does:
Omnitrope is used to increase growth hormone levels in children and adults unable to produce adequate amounts naturally.
Omnitrope may produce bone growth in children where the ends of the long bones have not yet hardened. In both adults and children requiring growth hormone replacement, Omnitrope helps in the development of muscles and causes fat to be used for energy. In adults with growth hormone deficiency, Omnitrope plays an important role in maintaining an improved ratio of body fat to lean mass.

When it should <u>not</u> be used:

- You are allergic (hypersensitive) to somatropin or any of the other ingredients of Omnitrope.
- You have an active tumour. Tumours must be inactive and you must have finished your anti-tumour treatment before you start using Omnitrope.
- You are seriously ill (for example, complications following open heart surgery, abdominal surgery, acute respiratory failure, accidental trauma or similar conditions). If you are about to have, or have had, a major operation, or go into hospital for any reason, tell your doctor and remind the other doctors you are seeing that you use growth hormone.
- Omnitrope has been prescribed to stimulate growth but you have already stopped growing (the growth plates on your long bones are closed).
- In patients with Prader-Willi syndrome who are very obese or have severe breathing 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: severe obesity, breathing problems, colds or lung infections.
- In patients with diabetic retinopathy, a complication of diabetes that results from damage to the blood vessels of the light-sensitive tissue at the back of the eye (retina).
- If you or your child are allergic to benzyl alcohol.

What the medicinal ingredient is:
Somatropin (recombinant human growth hormone)

What the important non-medicinal ingredients are:
Omnitrope Lyophilized Powder:
Glycine, disodium hydrogen phosphate, sodium dihydrogen phosphate.

Diluent Cartridge:
Bacteriostatic Water for Injection USP (benzyl alcohol preserved)

What dosage forms it comes in:
Omnitrope (somatropin for injection) is supplied as follows:
Lyophilized powder: 5.8 mg/vial

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- **Patients with acute critical illness suffering complications following open-heart surgery, abdominal surgery, multiple accidental trauma, acute respiratory failure or similar conditions should not be treated with somatropin** (See WARNINGS AND PRECAUTIONS - perioperative considerations).
- **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, breathing problems, or colds and lung infections** (See WARNINGS AND PRECAUTIONS Congenital Disorders).

Omnitrope therapy should be carried out under the regular guidance of a doctor who is experienced in the diagnosis and management of patients with growth hormone deficiency.

BEFORE you use Omnitrope talk to your doctor or pharmacist:

- If the patient is at risk of developing diabetes, the doctor will need to monitor their blood sugar level during treatment with Omnitrope.
- If the patient has diabetes, they should closely monitor their blood sugar level during treatment with Omnitrope and discuss the results with their doctor to determine whether they need to change the dose of their medicines to treat diabetes.
- If the patient is receiving treatment with thyroid hormones it may be necessary to adjust their thyroid hormone dose.
- If the patient is taking growth hormone to stimulate growth and walk with a limp or if they start to limp during their growth hormone treatment due to pain in their hip, they should inform their doctor.
- If the patient develops a strong headache, visual disturbances or vomiting they should inform their doctor about it.
- If the patient is receiving Omnitrope for growth hormone deficiency following a previous tumour, they should be examined regularly for recurrence of the tumour.
- If the patient is a survivor of childhood cancer.
- If the patient, especially a child, develops severe abdominal pain (inflammation of the pancreas).
- If the patient is, or plans to become pregnant or is breastfeeding.
- If the patient develop a limp while being treated with Omnitrope.
- If the patient has Turner syndrome and develops an ear infection or headaches her doctor should be told about these problems.
- If the patient has hypopituitarism and is receiving standard hormone replacement therapy, the doctor should monitor the hormone replacement therapy closely during omnitrope treatment.
- If you or your child are allergic to benzyl alcohol. Omnitrope 5.8 mg/vial Lyophilized Powder requires reconstitution with a diluent that contains benzyl alcohol.

After starting Omnitrope treatment some patients may need to start thyroid hormone replacement.

Progression of pre-existing scoliosis (curvature of the spine) can occur in children who have rapid growth.

The patient should not use Omnitrope if they are pregnant or are trying to become pregnant.

INTERACTIONS WITH THIS MEDICATION

Steroid hormones (Glucocorticoids) such as cortisone or prednisone may decrease the effects of Omnitrope. If you or your child are receiving concomitant glucocorticoid (steroid) therapy contact your doctor. Steroid doses may need to be adjusted.

Omnitrope may affect your or your child's body's response to insulin, and blood sugar levels may increase. Contact your doctor if you/your child have diabetes. It may be necessary to adjust the dosage of diabetes medications.

You should tell the doctor or nurse about all medicines that you/your child are taking, even those obtained without a doctor's prescription.

PROPER USE OF THIS MEDICATION

Recommended dosage
The dose depends on your size, the condition for which you are being treated and how well growth hormone works for you. Everyone is different. Your doctor will advise you about your individualized dose of Omnitrope in milligrams (mg) from either your body weight in kilograms (kg), as well as your treatment schedule. Do not change the dosage and treatment schedule without consulting your doctor.

Children with growth hormone deficiency:
0.16-0.24 mg/kg body weight per week. Higher doses can be used. When growth hormone deficiency continues into adolescence, Omnitrope should be continued until completion of physical development.

Children with Turner syndrome:
0.33 mg/kg body weight per week.

Children with idiopathic short stature:
UP TO 0.47 mg/kg body weight per week

Children born smaller or lighter than expected and with growth disturbance:
UP TO 0.48 mg/kg body weight per week. Your doctor will determine the most appropriate dose and length of treatment. Treatment should be discontinued if: i) after the first year if you are not responding or ii) if you have reached your final height and stopped growing.

Adults with growth hormone deficiency:
You should start with 0.15-0.3 mg per day.
This dosage should be gradually increased or decreased according to blood test results as well as clinical response and side effects.

Follow the instructions given to you by your doctor

Injecting Omnitrope
Omnitrope is intended for subcutaneous use. This means that it is injected through a short injection needle into the fatty tissue just under your skin. Your doctor should have already shown you how to use Omnitrope. Always inject Omnitrope exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

If you use more Omnitrope than you should
If you inject much more than you should, contact your doctor or pharmacist as soon as possible. Your blood sugar level could fall too low and later rise too high. You might feel shaky, sweaty, sleepy or "not yourself", and you might faint.

If you forget to use Omnitrope
Do not use a double dose to make up for a forgotten dose. It is best to use your growth hormone regularly. If you forget to use a dose, have your next injection at the usual time the next day. Keep a note of any missed injections and tell your doctor at your next check-up.

If you stop using Omnitrope
Ask for advice from your doctor before you stop using Omnitrope.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

Overdosage:
Call your doctor immediately if you or your child take more than the amount of Omnitrope prescribed by your doctor.

Over-dosing growth hormone for several months or years may cause a disease called acromegaly, which causes bones to over-grow and can be fatal. Never share your medication

In case of drug overdose, contact a healthcare 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.

Note: Do not reconstitute Omnitrope or inject it, until you have been taught the proper technique by your healthcare provider and you understand the instructions. Ask your healthcare provider or pharmacist if you have any questions about injecting OMNITROPE.

INSTRUCTIONS FOR OMNITROPE 5.8 MG/VIAL

The dosage of Omnitrope must be adjusted for the individual patient. The weekly dose should be divided into daily subcutaneous (just under the skin) injections (administered preferably in the evening). Omnitrope may be given in the thigh, buttocks, or abdomen; the site of SC injections should be rotated daily to help prevent lipoatrophy.

The following instructions explain how to inject Omnitrope 5.8 mg/vial:

Do not inject Omnitrope yourself until you have been taught the proper technique by your healthcare provider and you understand the instructions.

- Omnitrope 5.8 mg/vial is for multiple use.
- The concentration of Omnitrope after reconstitution is 5.0 mg/mL.
- After reconstitution, Omnitrope solution contains a preservative and should not be used in newborns.
- Omnitrope solution is for subcutaneous (just under the skin) injection.
- The injection sites should be rotated daily to help prevent lipoatrophy (local reduction of fatty tissue under the skin).

Preparation
Collect necessary items before you begin:

- a vial with 5.8 mg Omnitrope powder for solution for injection.
- a cartridge with diluent (Bacteriostatic Water for Injection containing benzyl alcohol as preservative).
- a transfer set for mixing and transferring the reconstituted solution back into the cartridge.
- the Omnitrope Pen L, an injection device specifically developed for use with Omnitrope 5.0 mg/mL reconstituted solution for injection (not supplied in the pack; see Instructions for Use of the transfer set and of the injection device).
- 2 alcohol swabs (not supplied in the pack).

Wash your hands before you start with the next steps.

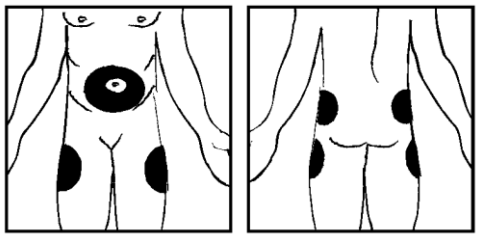
Reconstituting Omnitrope 5.8 mg/vial

- Remove the protective cap from the vial. With one alcohol swab, disinfect both the rubber membrane of the vial with powder and the cartridge containing diluent.

- Use the transfer set to transfer all of the diluent from the cartridge into the vial. Follow the directions that come with the transfer set.
- Gently swirl the reconstituted vial until the content is completely dissolved. **Do not shake**.
- If the solution is cloudy or contains particles, it should not be used. The solution must be clear and colourless after mixing.
- Transfer all of the dissolved solution back into the cartridge using the transfer set.

Injecting Omnitrope 5.8 mg/vial

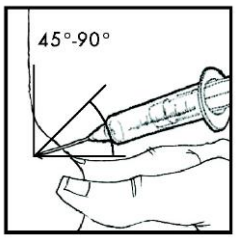
- Put the cartridge with the Omnitrope solution into the Pen L for injection. Follow the Instructions for Use of the Pen Injector.
- Eliminate any air bubbles.
- Select the site of injection. The best sites of injection are tissues with a layer of fat between skin and muscle, such as the thigh, buttocks, or abdomen as in the pictures shown below. **Do not inject near your belly button (navel) or waistline.**



- Make sure you rotate the injection sites on your body. Inject at least 1 cm from your last injection site and change the places on your body where you inject, as you have been taught.
- Before you make an injection, clean your skin well with an alcohol swab. Wait for the area to air dry.

- Insert the needle into the skin the way your doctor has taught you.

- With one hand, pinch a fold of loose skin at the injection site. With your other hand, hold the Pen L as you would a pencil. Insert the needle into the pinched skin straight in or at a slight angle (an angle of 45° to 90°).



- Pull the needle straight out of the skin. After injection, press the injection site with a small bandage or sterile gauze if needed for bleeding, for several seconds. Do not massage or rub the injection site.

After Injecting Omnitrope 5.8 mg/vial

- After injection, press the injection site with a small bandage or sterile gauze for several seconds. Do not massage the injection site.
- Remove the needle from the pen using the outer needle cap and discard the needle. This will keep Omnitrope sterile and prevent leaking. It will also stop air from going back into the pen and the needle clogging up. Do not share your needles. Do not share your pen.
- Leave the cartridge in the pen, replace the pen cap and store in a refrigerator (at 2-8°C) and discard any unused solution 28 days after reconstitution.
- The solution should be clear after removal from the refrigerator. **Do not use if the solution is cloudy or contains particles.**

Do not inject Omnitrope yourself until you have been taught the proper technique by your healthcare provider and you understand the instructions.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, Omnitrope can cause side effects, although not everybody experiences them. Please ask your doctor for advice when you experience any of the symptoms described below.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	General disorders and reactions at the injection site. In children: temporary local skin reactions.		✓	
	Musculoskeletal system, connective tissues, bones. In adults: stiffness of the limbs, joints and muscle pain.		✓	
	Nervous System. In adults: numbness, tingling or pain in arms, legs or face, or trouble		✓	

	with vision.			
	Increased blood sugar. In adults: mild edema (tissue swelling).		✓	
	Disorders of the immune system such as development of antibodies.		✓	
Uncommon	Musculoskeletal system, connective tissues, bones. In children: stiffness of the limbs, joints and muscle pain.		✓	
	Nervous System. -In children: numbness, tingling or pain in arms, legs or face, or trouble with vision -In adults: carpal tunnel syndrome		✓	
	Increased blood sugar, in children: mild edema (tissue swelling).		✓	
Rare	Nervous System such as: benign intracranial hypertension.		✓	
	Increased blood sugar such as: Diabetes mellitus.		✓	
	Allergic reactions		✓	
Very Rare	Leukemia – Benign and malignant cancers.		✓	

Slipped capital femoral epiphysis and Legg-Calve-Perthes disease may be considered by your doctor if discomfort or pain in the hip or knee is experienced whilst being treated with Omnitrope.

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

HOW TO STORE IT

- Omnitrope **must** be refrigerated between 2 - 8°C, both in powder form and after reconstitution.
- Discard any unused solution 28 days after reconstitution.
- Do NOT freeze.
- Omnitrope is light sensitive and should be stored in the original package.
- Do NOT use after the expiry date on the label and carton.
- Do NOT use Omnitrope if the solution is cloudy or contains particles.
- Keep out of reach and sight 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
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 0701E
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 side effects, 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 obtained at www.sandoz.ca or by contacting the sponsor, Sandoz Canada Inc., at: 1-800-361-3062 or

by written request at:

Sandoz Canada Inc.

145, Jules-Léger

Boucherville, (Québec), Canada

J4B 7K8

or by e-mail at :
medinfo@sandoz.com

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Boucherville, Québec, Canada J4B 7K8

Questions or Concerns: 1-800-361-3062

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PART III: CONSUMER INFORMATION (Solution for Injection)

PrOMNITROPE®
AWM nee trope
(Somatropin for Injection)
Solution for Injection: 5.0 mg/1.5 mL, 10 mg/1.5 mL and 15 mg/1.5 mL

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

ABOUT THIS MEDICATION

What the medication is used for:

In children, Omnitrope is used to treat the following growth problems:

- If you are not growing properly and you do not have enough of your own growth hormone.
- If you have Turner syndrome. Turner syndrome is a chromosomal error in girls that can affect growth - your doctor will have told you if you have this.
- If you were small or too light at birth. Growth hormone may help you grow taller if you have not been able to catch up or maintain normal growth by two years of age or later.
- If you have idiopathic (unknown cause) short stature.

In adults, Omnitrope is used to treat persons with pronounced growth hormone deficiency. This can start during adult life, or it can continue from childhood.

If you have been treated with Omnitrope for growth hormone deficiency during childhood, your growth hormone status will be retested after completion of growth. If severe growth hormone deficiency is confirmed, your doctor will propose continuation of Omnitrope treatment.

What it does:
Omnitrope is used to increase growth hormone levels in children and adults unable to produce adequate amounts naturally.

Omnitrope may produce bone growth in children where the ends of the long bones have not yet hardened. In both adults and children requiring growth hormone replacement, Omnitrope helps in the development of muscles and causes fat to be used for energy. In adults with growth hormone deficiency, Omnitrope plays an important role in maintaining an improved ratio of body fat to lean mass.

When it should <u>not</u> be used:

- You are allergic (hypersensitive) to somatropin or any of the other ingredients of Omnitrope.
- You have an active tumour. Tumours must be inactive and you must have finished your anti-tumour treatment before you start using Omnitrope.
- You are seriously ill (for example, complications following open heart surgery, abdominal surgery, acute respiratory failure, accidental trauma or similar conditions). If you are about to have, or have had, a major operation, or go into hospital for any reason, tell your doctor and remind the other doctors you are seeing that you use growth hormone.
- Omnitrope has been prescribed to stimulate growth but you have already stopped growing (the growth plates on your long bones are closed).
- In patients with Prader-Willi syndrome who are very obese or have severe breathing 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: severe obesity, breathing problems, colds or lung infections.
- In patients with diabetic retinopathy, a complication of diabetes that results from damage to the blood vessels of the light-sensitive tissue at the back of the eye (retina).
- If you or your child are allergic to benzyl alcohol.

What the medicinal ingredient is:
Somatropin (recombinant human growth hormone)

What the important non - medicinal ingredients are:
5.0 mg/1.5 mL cartridge contains: disodium hydrogen phosphate heptahydrate, sodium dihydrogen phosphate dihydrate, mannitol, poloxamer 188, benzyl alcohol, water for injection.

10.0 mg/1.5 mL cartridge contains: disodium hydrogen phosphate heptahydrate, sodium dihydrogen phosphate dihydrate, glycine, poloxamer 188, phenol, water for injection.

15.0 mg/1.5 mL cartridge contains: disodium hydrogen phosphate heptahydrate, sodium dihydrogen phosphate dihydrate, soduium chloride, poloxamer 188, phenol, water for injection.

What dosage forms it comes in:
Omnitrope (somatropin for injection) is supplied as a solution: 5.0 mg/1.5 mL cartridge, 10 mg/1.5 mL cartridge and 15 mg/1.5 mL cartridge.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- **Patients with acute critical illness suffering complications following open-heart surgery, abdominal surgery, multiple accidental trauma, acute respiratory failure or similar conditions should not be treated with somatropin** (See WARNINGS AND PRECAUTIONS - perioperative considerations).
- **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, breathing problems, or colds and lung infections (See WARNINGS AND PRECAUTIONS Congenital Disorders).

Omnitrope therapy should be carried out under the regular guidance of a doctor who is experienced in the diagnosis and management of patients with growth hormone deficiency.

BEFORE you use Omnitrope talk to your doctor or pharmacist:

- If the patient is at risk of developing diabetes, the doctor will need to monitor their blood sugar level during treatment with Omnitrope.
- If the patient has diabetes, they should closely monitor their blood sugar level during treatment with Omnitrope and discuss the results with their doctor to determine whether they need to change the dose of their medicines to treat diabetes.
- If the patient is receiving treatment with thyroid hormones it may be necessary to adjust their thyroid hormone dose.
- If the patient is taking growth hormone to stimulate growth and walk with a limp or if they start to limp during their growth hormone treatment due to pain in their hip, they should inform their doctor.
- If the patient develops a strong headache, visual disturbances or vomiting they should inform their doctor about it.
- If the patient is receiving Omnitrope for growth hormone deficiency following a previous tumour, they should be examined regularly for recurrence of the tumour.
- If the patient is a survivor of childhood cancer.
- If the patient, especially a child, develops severe abdominal pain (inflammation of the pancreas).
- If the patient is, or plans to become pregnant or is breastfeeding.
- If the patient develop a limp while being treated with Omnitrope.
- If the patient has Turner syndrome and develops an ear infection or headaches her doctor should be told about these problems.
- If the patient has hypopituitarism and is receiving standard hormone replacement therapy, the doctor should monitor the hormone replacement therapy closely during omnitrope treatment.
- If you or your child are allergic to benzyl alcohol.

After starting Omnitrope treatment some patients may need to start thyroid hormone replacement.

Progression of pre-existing scoliosis (curvature of the spine) can occur in children who have rapid growth.

The patient should not use Omnitrope if they are pregnant or are trying to become pregnant.

INTERACTIONS WITH THIS MEDICATION

Steroid hormones (Glucocorticoids) such as cortisone or prednisone may decrease the effects of Omnitrope. If you/your child are receiving concomitant glucocorticoid (steroid) therapy contact your doctor. Steroid doses may need to be adjusted.

Omnitrope may affect your or your child's body's response to insulin, and blood sugar levels may increase. Contact your doctor if you/your child have diabetes. It may be necessary to adjust the dosage of diabetes medications.

You should tell the doctor or nurse about all medicines that the patient is taking, even those obtained without a doctor's prescription.

PROPER USE OF THIS MEDICATION

Recommended dosage
The dose depends on your size, the condition for which you are being treated and how well growth hormone works for you. Everyone is different. Your doctor will advise you about your individualized dose of Omnitrope in milligrams (mg) from either your body weight in kilograms (kg), as well as your treatment schedule. Do not change the dosage and treatment schedule without consulting your doctor.

Children with growth hormone deficiency:
0.16-0.24 mg/kg body weight per week. Higher doses can be used. When growth hormone deficiency continues into adolescence, Omnitrope should be continued until completion of physical development.

Children with Turner syndrome:
0.33 mg/kg body weight per week.

Children with idiopathic short stature:
UP TO 0.47 mg/kg body weight per week

Children born smaller or lighter than expected and with growth disturbance:
UP TO 0.48 mg/kg body weight per week. Your doctor will determine the most appropriate dose and length of treatment. Treatment should be discontinued: i) if after the first year if you are not responding or ii) if you have reached your final height and stopped growing.

Adults with growth hormone deficiency:
You should start with 0.15-0.3 mg per day.
This dosage should be gradually increased or decreased according to blood test results as well as clinical response and side effects. Follow the instructions given to you by your doctor

Injecting Omnitrope
Omnitrope is intended for subcutaneous use. This means that it is injected through a short injection needle into the fatty tissue just under your skin. Your doctor should have already shown you how to use Omnitrope. Always inject Omnitrope exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

If you use more Omnitrope than you should
If you inject much more than you should, contact your doctor or pharmacist as soon as possible. Your blood sugar level could fall too low and later rise too high. You might feel shaky, sweaty, sleepy or "not yourself", and you might faint.

If you forget to use Omnitrope
Do not use a double dose to make up for a forgotten dose. It is best to use your growth hormone regularly. If you forget to use a dose, have your next injection at the usual time the next day. Keep a note of any missed injections and tell your doctor at your next check-up.

If you stop using Omnitrope
Ask for advice from your doctor before you stop using Omnitrope.

Overdose:
Call your doctor **immediately** if you/your child take more than the amount of Omnitrope prescribed by your doctor.

Over-dosing growth hormone for several months or years may cause a disease called acromegaly, which causes bones to over-grow and can be fatal. Never share your medication

In case of drug overdose, contact a healthcare 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.

INSTRUCTIONS FOR USE OMNITROPE 5.0 mg/1.5mL (somatropin for injection)

How to inject Omnitrope 5.0 mg/1.5 mL
The following instructions explain how to inject Omnitrope 5.0 mg/1.5 mL yourself. Please read the instructions carefully and follow them step by step. Your doctor or other suitably qualified healthcare professionals will show you how to inject Omnitrope. Do not attempt to inject unless you are sure you understand the procedure and requirements for injection.

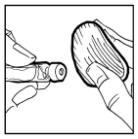
- Omnitrope is given as a subcutaneous (just under the skin) injection.
- Carefully inspect the solution before injecting it and use only if clear and colourless.
- Change the injection sites to minimize the risk of local lipoatrophy (local reduction of fatty tissue under the skin).

Preparation
Collect necessary items before you begin:

- a cartridge with Omnitrope 5.0 mg/1.5 mL solution for injection.
- the Omnitrope® Surepal 5, an injection device specifically developed for use with Omnitrope 5.0 mg/1.5 mL solution for injection (not supplied in the pack; see Instructions for Use provided with the Omnitrope® Surepal 5).
- a pen needle for subcutaneous (just under the skin) injection.
- 2 alcohol swabs (not supplied in the pack).

Wash your hands before you continue with the next steps.

Injecting Omnitrope
- With an alcohol swab, disinfect the rubber membrane of the cartridge.
- The contents must be clear and colourless.



- Insert the cartridge into the pen for injection. Follow the Instructions for Use of the pen injector. To set up the pen dial the dose.
- Select the site of injection. The best sites for injection are tissues with a layer of fat between skin and muscle, such as the thigh, buttocks, or abdomen (except the navel or waistline).
- Make sure you inject at least 1 cm from your last injection site and that you change the places where you inject, as you have been taught.
- Before you make an injection, clean your skin well with an alcohol swab. Wait for the area to dry.

- Insert the needle into the skin in the way your doctor has taught you.

After Injecting
- After injection, press the injection site with a small bandage or sterile gauze for several seconds. Do not massage the injection site.
- Take the needle off the pen using the outer needle cap, and discard the needle. This will keep the Omnitrope solution sterile and prevent leaking. It will also stop air going back into the pen and the needle clogging up. Do not share your needles. Do not share your pen.

- Leave the cartridge in the pen, put the cap on the pen, and store it in the refrigerator.
- The solution should be clear after removal from the refrigerator. **Do not use if the solution is cloudy or contains particles.**
- After the first injection, the cartridge should remain in the pen injector in a refrigerator between 2°C to 8°C for a maximum of 28 days.

INSTRUCTIONS FOR USE OMNITROPE 10.0 mg/1.5 mL (somatropin for injection)

How to inject Omnitrope 10.0 mg/1.5 mL
The following instructions explain how to inject Omnitrope 10.0 mg/1.5 mL yourself. Please read the instructions carefully and follow them step by step. Your doctor or other suitably qualified healthcare professionals will show you how to inject Omnitrope. Do not attempt to inject unless you are sure you understand the procedure and requirements for injection.

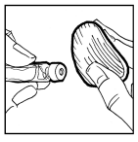
- Omnitrope is given as a subcutaneous (just under the skin) injection.
- Carefully inspect the solution before injecting it and use only if clear and colourless.
- Change the injection sites to minimise the risk of local lipoatrophy (local reduction of fatty tissue under the skin).

Preparation
Collect necessary items before you begin:

- a cartridge with Omnitrope 10.0 mg/1.5 mL solution for injection.
- the Omnitrope® Surepal 10, an injection device specifically developed for use with Omnitrope 10.0 mg/1.5 mL solution for injection (not supplied in the pack; see Instructions for Use provided with the Omnitrope® Surepal 10).
- a pen needle for subcutaneous (just under the skin) injection.
- 2 alcohol swabs (not supplied in the pack).

Wash your hands before you continue with the next steps.

Injecting Omnitrope
- With an alcohol swab, disinfect the rubber membrane of the cartridge.
- The contents must be clear and colourless.



- Insert the cartridge into the pen for injection. Follow the Instructions for Use of the pen injector. To set up the pen, dial the dose.
- Select the site of injection. The best sites for injection are tissues with a layer of fat between skin and muscle, such as the thigh, buttocks, or abdomen (except the navel or waistline).
- Make sure you inject at least 1 cm from your last injection site and that you change the places where you inject, as you have been taught.
- Before you make an injection, clean your skin well with an alcohol swab. Wait for the area to dry.

- Insert the needle into the skin in the way your doctor has taught you.

After Injecting
- After injection, press the injection site with a small bandage or sterile gauze for several seconds. Do not massage the injection site.
- Take the needle off the pen using the outer needle cap, and discard the needle. This will keep the Omnitrope solution sterile and prevent leaking. It will also stop air going back into the pen and the needle clogging up. Do not share your needles. Do not share your pen.
- Leave the cartridge in the pen, put the cap on the pen, and store it in the refrigerator.
- The solution should be clear after removal from the refrigerator. **Do not use if the solution is cloudy or contains particles.**
- After the first injection, the cartridge should remain in the pen injector in a refrigerator between 2°C to 8°C for a maximum of 28 days.

INSTRUCTIONS FOR USE OMNITROPE 15.0 mg/1.5 mL (somatropin for injection)

How to inject Omnitrope 15.0 mg/1.5 mL
The following instructions explain how to inject Omnitrope 15.0 mg/1.5 mL yourself. Please read the instructions carefully and follow them step by step. Your doctor or other suitably qualified healthcare professionals will show you how to inject Omnitrope. Do not attempt to inject unless you are sure you understand the procedure and requirements for injection.

- Omnitrope is given as a subcutaneous (just under the skin) injection.
- Carefully inspect the solution before injecting it and use only if clear and colourless.
- Change the injection sites to minimise the risk of local lipoatrophy (local reduction of fatty tissue under the skin).

Preparation

Collect necessary items before you begin:

- a cartridge with Omnitrope 15.0 mg/1.5 mL solution for injection.
- the Omnitrope® Surepal 15, an injection device specifically developed for use with Omnitrope 15.0 mg/1.5 mL solution for injection (not supplied in the pack; see Instructions for Use provided with the Omnitrope® Surepal 15).
- a pen needle for subcutaneous (just under the skin) injection.
- 2 alcohol swabs (not supplied in the pack).

Wash your hands before you continue with the next steps.

Injecting Omnitrope

- With an alcohol swab, disinfect the rubber membrane of the cartridge.
- The contents must be clear and colourless**.**

- Insert the cartridge into the pen for injection. Follow the Instructions for Use of the pen injector. To set up the pen, dial the dose.
- Select the site of injection. The best sites for injection are tissues with a layer of fat between skin and muscle, such as the thigh, buttocks, or abdomen (except the navel or waistline).
- Make sure you inject at least 1 cm from your last injection site and that you change the places where you inject, as you have been taught.
- Before you make an injection, clean your skin well with an alcohol swab. Wait for the area to dry.

- Insert the needle into the skin in the way your doctor has taught you**.**

After Injecting

- After injection, press the injection site with a small bandage or sterile gauze for several seconds. Do not massage the injection site.
- Take the needle off the pen using the outer needle cap, and discard the needle. This will keep the Omnitrope solution sterile and prevent leaking. It will also stop air going back into the pen and the needle clogging up. Do not share your needles. Do not share your pen.
- Leave the cartridge in the pen, put the cap on the pen, and store it in the refrigerator.
- The solution should be clear after removal from the refrigerator. **Do not use if the solution is cloudy or contains particles.**
- After the first injection, the cartridge should remain in the pen injector in a refrigerator between 2°C to 8°C for a maximum of 28 days.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, Omnitrope can cause side effects, although not everybody experiences them. Please ask your doctor for advice when you experience any of the symptoms described below.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	General disorders and reactions at the injection site. In children: temporary local skin reactions.		✓	
	Musculoskeletal system, connective tissues, bones. In adults: stiffness of the limbs, joints and muscle pain.		✓	
	Nervous System. In adults: numbness, tingling or pain in arms, legs or face, or trouble with vision.		✓	
	Increased blood sugar. In adults: mild edema (tissue swelling).		✓	
	Disorders of the immune system such as development of antibodies.		✓	
Uncommon	Musculoskeletal system, connective tissues, bones. In children: stiffness of the limbs, joints and muscle pain.		✓	
	Nervous System. In children: numbness, tingling or pain in arms, legs or face, or trouble with vision In adults: carpal tunnel syndrome		✓	
	Increased blood sugar. In children: mild edema (tissue swelling) .		✓	

Rare	Nervous System such as: benign intracranial hypertension.		✓	
	Increased blood sugar such as: Diabetes mellitus.		✓	
	Allergic reactions		✓	
Very Rare	Leukemia – Benign and malignant cancers.		✓	

Slipped capital femoral epiphysis and Legg-Calve-Perthes disease may be considered by your doctor if discomfort or pain in the hip or knee is experienced whilst being treated with Omnitrope.

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

HOW TO STORE IT

- Omnitrope **must** be refrigerated between 2 and 8°C.
- Omnitrope solution must be used within 28 days after the first injection.
- Do NOT freeze.
- Omnitrope is light sensitive and should be stored in the original package.
- Do NOT use after the expiry date on the label and carton.
- Do NOT use Omnitrope if the solution is cloudy or contains particles.
- After the first injection, the cartridge should remain in the pen injector and must be kept in a refrigerator between 2 and 8°C (see Instructions for Use of the pen injector).
- Keep out of reach and sight 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
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 1908CE
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 side effects, 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 obtained at www.sandoz.ca or by contacting the sponsor, Sandoz Canada Inc., at: 1-800-361-3062 or

by written request at:

Sandoz Canada Inc.

145, Jules-Léger

Boucherville, (Québec), Canada

J4B 7K8

or by e-mail at :

medinfo@sandoz.com

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Questions or Concerns: 1-800-361-3062

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