PART III: CONSUMER INFORMATION

PrSEROSTIM® 5 mg/vial
(Somatropin for injection)

This leaflet is Part III of a three-part "Product Monograph" published when the drug is approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SEROSTIM. Contact your health care professional if you have any questions about the drug.

ABOUT THIS MEDICATION

What is SEROSTIM used for?
SEROSTIM is indicated for the treatment of HIV wasting associated with catabolism, weight loss or cachexia.

What does SEROSTIM do?
HIV-associated wasting is a metabolic disorder characterized by specific abnormalities of intermediary metabolism resulting in weight loss, inappropriate depletion of lean body mass (LBM), and paradoxical preservation of body fat. LBM includes primarily skeletal muscle, organ tissue, blood and blood constituents. LBM depletion results in muscle weakness, organ failure, immune deficiency, general inanition and death. Unlike nutritional intervention for HIV-associated wasting, in which supplemental calories are converted predominantly to body fat which is essentially inert in day-to-day metabolic balance, the anabolic and anti-catabolic effects of SEROSTIM treatment resulted in a prompt and sustained increase in LBM and a decrease in body fat with a significant increase in body weight due to the dominant effect of LBM gain.

When should SEROSTIM not be used?
SEROSTIM should not be used in the following patient groups:

- patients with acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or patients having acute respiratory failure.
- in the presence of any progression of underlying intracranial tumour. Intracranial tumour should be inactive and anti-malignancy treatment must be completed with evidence of remission prior to instituting therapy and SEROSTIM should be discontinued if there is evidence of recurrent activity. Patients should be examined frequently for progression or recurrence of the underlying disease process.
- patients who are hypersensitive to growth hormone or to any ingredient in the formulation, or component of the container.
- patients with active neoplasia (either newly diagnosed or recurrent). Any anti-tumour therapy should be completed prior to starting therapy with SEROSTIM and should be discontinued if there is evidence of recurrent tumor growth.
- patients with diabetes mellitus.
- patients with proliferative or preproliferative diabetic retinopathy.

The medicinal ingredient in SEROSTIM:
The common name of the active ingredient in SEROSTIM is somatropin.

The nonmedicinal ingredients in SEROSTIM:
Each vial of SEROSTIM contains the following non-medicinal ingredients: sucrose, phosphoric acid and sodium hydroxide.

The diluent which comes with SEROSTIM 5 mg/vial is sterile water.

What dosage forms of SEROSTIM are available?
SEROSTIM is available as a sterile, non-pyrogenic, lyophilized powder.

SEROSTIM is available in 5 mg vials each with vials of diluent (Sterile Water for Injection).

WARNINGS AND PRECAUTIONS

Before you use SEROSTIM talk to your doctor or pharmacist if:

- you are hypersensitive to somatropin or to any of the other ingredients of SEROSTIM
- you are pregnant or breastfeeding
- you have an acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or to patients having acute respiratory failure
- you develop hyperglycemia
- you experience increased tissue turgor (non-edematous swelling, particularly in the hands and feet) and musculoskeletal discomfort (pain, swelling and/or stiffness)
- you experience carpal tunnel syndrome

MEDICATION INTERACTIONS

During clinical trials in which all patients received anti-retroviral therapy there were no detectable increases in plasma viral load following SEROSTIM therapy. Patients with AIDS wasting considered for treatment with SEROSTIM should also receive approved anti-retroviral therapy.

No formal interaction studies have been performed in patients treated with SEROSTIM.

Interactions with food, herbal products and laboratory tests have not been established.

PROPER USE OF THIS MEDICATION

Usual dose:
SEROSTIM should be administered subcutaneously daily at bedtime according to the following dosage recommendations:

Weight Range	Dose*
> 55 kg	6 mg SC daily
45-55 kg	5 mg SC daily
35-45 kg	4 mg SC daily

*Based on an approximate daily dosage of 0.1mg/kg

In patients who weigh less than 35 kg, SEROSTIM should be administered at a dose of 0.1 mg/kg subcutaneously daily at bedtime.

Treatment with the medicinal product should be initiated under the supervision of a specialised physician.

Preparing SEROSTIM for Administration
Here are the things you will need before you inject SEROSTIM:

- 3 alcohol swabs
- Cotton swab
- 3 cc syringe & 23 gauge needle for mixing
- BD insulin syringe for injection
- 1 vial of SEROSTIM
- Diluent vial (You need this sterile liquid - the diluent - to dissolve the SEROSTIM powder and make it injectable.)
- Syringe safety disposal container for used vials and needles

Always use unopened, sterile needles and syringes and keep the needles capped until needed.

TIP: Your doctor or nurse will explain how much diluent to add to the vial of SEROSTIM and how much SEROSTIM to inject.

Getting Ready to use SEROSTIM
1. Begin by choosing a clean flat surface (like a kitchen or bathroom counter).
2. Wash your hands thoroughly with soap and water. This helps prevent infection.
3. Check the expiration date of your SEROSTIM vial.

Drawing Up the Diluent
1. Carefully twist the needle cover off the long needle syringe.
2. Pull out the plunger to the amount recommended by your doctor or nurse. This brings air into the syringe.
3. Remove the flip-off cap from the diluent vial and discard. Wipe the rubber stopper of the vial with an alcohol swab.
4. Hold the vial firmly on the countertop. Put the needle into the stopper of the SEROSTIM diluent vial. Push the plunger of the syringe and inject the air into the vial.
5. Turn the vial upside down. Make sure the needle tip stays in the liquid. Pull back on the plunger until the marks on the barrel of the syringe show that the amount of the diluent suggested by your doctor or nurse has been drawn out.
6. If air bubbles appear in the syringe, gently push the plunger into the syringe to send the air into the vial. You may have to tap the syringe lightly so you can push the bubbles out. Draw up more diluent, if needed, until you have the amount your doctor has prescribed.
7. Pull out the needle from the diluent.

TIP: Be careful not to touch the uncapped needle with your fingers or let the needle touch anything.

Mixing SEROSTIM
1. Remove the flip-off cap from the SEROSTIM vial and discard. Wipe the rubber stopper of the vial with an alcohol swab.
2. With the same syringe, put the long needle into the stopper of the SEROSTIM vial. Gently place the needle tip against the vial wall. Slowly inject the diluent, aiming the stream of diluent at the glass wall of the vial. DO NOT AIM THE STREAM AT THE WHITE POWDER at the bottom of the vial.
3. Take out the needle and throw it away in the safety container.
4. Gently swirl (don't shake) the vial until the powder is completely dissolved. The SEROSTIM mixture should be clear. If it stays hazy, cloudy or has pieces floating in it after mixing, do not use it.

TIP: If SEROSTIM becomes cloudy after mixing, return it to your pharmacist or nurse.

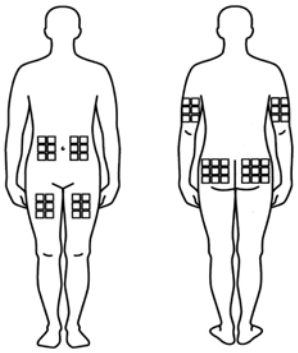
Preparing SEROSTIM for Injection
1. Re-wipe the rubber stopper of the SEROSTIM vial with an alcohol swab.
2. Pick up the insulin syringe with the short needle and carefully take off the needle cover.
3. Pull out the plunger to the amount recommended by your doctor or nurse. This brings air into the syringe.
4. Slowly insert the needle straight through the center of the rubber stopper of the vial of newly mixed SEROSTIM. Gently push the plunger to inject air into the vial.
5. Turn the vial upside down with the syringe needle still in it, holding the vial in one hand. Be sure the tip of the needle is in the solution. Using your other hand, slowly pull back on the plunger until the amount of SEROSTIM prescribed is in the syringe.
6. Remove the needle from the vial.
7. Hold the syringe straight up and tap gently. Put the plastic needle guard back until injection time. The injection should be given as soon after filling the syringe as possible. Do not store SEROSTIM in the syringe.

TIP: Be careful not to touch the uncapped needle with your fingers - or let the needle touch anything.

Picking an Injection Site
You should pick a different site to inject each day, rotating through arms, legs and abdomen. The buttocks can be used, as well (see Injection Site Diagram). Keep track of your injection

sites on a calendar. Using a site too often can lead to infection or irritation.

Injection Site Diagram



Injecting SEROSTIM

1. Clean the skin at the injection site with an alcohol swab using a circular motion.
   TIP: Let the skin dry after cleaning it with alcohol. This helps reduce stinging.
2. Remove the cap from the needle and, using the hand with which you write, pick up the syringe and hold it like a pencil.
3. Pinch up a generous fold of skin and hold it while quickly inserting the needle all the way in at a 90 degree angle to the skin. With your index finger, push the plunger in to inject the medication. Take as much time as you need to inject all the solution. You may wish to count to 5.
   TIP: When inserting the needle, you need very little force, but quick action.

4. As you release the skin from your grip, withdraw the needle at the same angle at which it was inserted. Place the cotton swab on the injection site and apply a gentle pressure.
5. Do not put the needle back in the needle guard. Carefully throw away the needle guard and all used needles and syringes in the safety container after a single use.

TIP: NEVER reuse a needle.

Disposal containers must be made of thick, puncture-proof plastic with a lid that fits firmly, such as an empty pop bottle. Containers may be returned to the clinic for disposal or you may wish to contact your pharmacy for further information regarding the safe disposal of used syringes.

Things to remember

1. Make injections routine - give the injection at the same time each evening before bedtime.
2. Before mixing, store vials at room temperature.
3. Vials of SEROSTIM reconstituted with the diluent provided (Sterile Water for Injection, USP) should be used immediately (within 3 hours), and any unused solution should be discarded.
4. Check the expiration date.
5. Do not use if it turns cloudy, lumpy or discoloured.
6. Make certain that the dosage is equal to the amount prescribed.
7. Rotate your injection sites each time, as discussed with your nurse.
8. If you are unsure about the mixing of the medication or if you are having difficulty with the injection procedure, contact your nurse or doctor.

Overdose

There is no known antidote to SEROSTIM or any specific treatment for SEROSTIM overdose other than withholding treatment and patient observation. In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions or effects and appropriate symptomatic treatment instituted immediately.

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

If you forget to take an injection on your usual day of the week, do not double your next injection. If you have forgotten more than one injection, contact your physician for advice on how to proceed.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common adverse reactions reported in the clinical trials and felt to be associated with SEROSTIM were musculoskeletal discomfort and increased tissue turgor (non-edematous swelling, particularly of the hands or feet). These symptoms were generally rated by investigators as mild to moderate in severity and usually subsided with continued treatment.

Clinical adverse events which occurred during the first 12 weeks of study in at least 10% of those who received SEROSTIM during the two placebo-controlled trials are listed below by treatment group.

Adverse Event	SEROSTIM	Placebo
	n=205	n=150
	%	%
Musculoskeletal discomfort	53.7	33.3
Fever	31.2	29.3
Increased tissue	27.3	2.7
Diarrhea	25.9	20
Neuropathy	25.9	17.3
Nausea	25.9	16
Headache	19	20.7
Abdominal pain	17.1	18.7
Fatigue	17.1	16
Leukopenia	15.1	24.7
Albuminuria	15.1	9.3
Granulocytopenia	14.1	21.3
Lymphadenopathy	14.1	16
Anorexia	12.2	8.7
Anemia	12.2	9.3
Vomiting	11.7	8.7
SGOT increased	11.7	12

Adverse Event	SEROSTIM	Placebo
	n=205	n=150
	%	%
Insomnia	11.2	9.3
Tachycardia	11.2	6
Hyperglycemia	10.2	6
SGPT increased	10.2	5.3

This is not a complete list of side effects. If you experience any unusual symptoms or side effects, you should report them to the doctor immediately. It is also wise to discuss the possibility of side effects with the doctor before beginning treatment.

HOW TO STORE SEROSTIM

Before reconstitution (mixing)
Lyophilized product:
Store SEROSTIM lyophilized product at or below 25 °C (room temperature).

Do not use SEROSTIM after the expiry date shown on label.

After reconstitution (mixing)
Reconstituted product:
When reconstituted with the diluent provided (Sterile Water for Injection, USP), the reconstituted solution should be administered immediately (within 3 hours). Although not recommended, it may be stored for up to 24 hours at 2-8 °C. As there is no preservative in this reconstituted solution, any unused solution should be discarded once the dose is given.

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 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.

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

MORE INFORMATION

This document plus the full Product Monograph, prepared for health care professionals can be found at: http://www.emdserono.ca or by calling EMD Serono at 1-877-724-9361.

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