



Take action for your patients with HIV-associated wasting or cachexia

# DON'T WASTE ANOTHER MOMENT

Serostim® (somatropin) is the only FDA-approved treatment indicated to increase lean body mass and body weight and improve physical endurance in HIV patients with wasting or cachexia. Concomitant antiretroviral therapy is necessary.

## Serostim® Weight-based Dosage Recommendations

The recommended dose of Serostim® is 0.1 mg/kg subcutaneously (SC) daily (up to 6 mg) at bedtime. The chart shows the body weight-based dosage recommendations.

Weight range	Dose
>55 kg (>121 lb)	6 mg* SC daily
45-55 kg (99-121 lb)	5 mg* SC daily
35-45 kg (75-99 lb)	4 mg* SC daily
<35 kg (<75 lb)	0.1 mg/kg SC daily

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



For patients at increased risk of adverse side effects potentially related to Serostim® treatment, dose reductions (i.e., reducing the total daily dose or the number of doses per week) could be considered.

- Treatment with Serostim® 0.1 mg/kg every other day was associated with fewer side effects, and resulted in a similar improvement in cycle ergometry work output (a measure of physical endurance), as compared with Serostim® 0.1 mg/kg daily.
- Although work output was similar, gains in weight and lean body mass observed with the 0.1 mg/kg dosage were lower than with the standard daily dosage.

## Reconstitution and Administration

Serostim® is available as 5 mg and 6 mg single dose vials and 4 mg multi-dose vial. Each Serostim® package contains 7 vials. Each vial of Serostim® 5 mg or 6 mg is reconstituted with 0.5 to 1 ml Sterile Water for Injection, USP. Each vial of Serostim® 4 mg is reconstituted in 0.5 to 1 ml of Bacteriostatic Water for Injection, USP (0.9% Benzyl Alcohol preserved). Serostim® can be administered using a standard sterile, disposable syringe and needle:

- 29G, ½" needles, 3-cc syringe, with 20G, 1" needles for reconstitution
- 30G, ½" needles, 3-cc syringe, with 20G, 1" needles for reconstitution

Please ensure that the prescription includes needles for both reconstitution and injection. Patients will require separate needles for mixing the product and administration.

## IMPORTANT SAFETY INFORMATION CONTRAINDICATIONS

**Acute Critical Illness:** Serostim® should not be initiated in patients with acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure.

**Active Malignancy:** Somatropin is contraindicated in the presence of active malignancy. Any preexisting malignancy should be inactive and its treatment complete prior to instituting therapy with somatropin. Discontinue somatropin if there is evidence of recurrent activity.

**Hypersensitivity:** Serostim® is contraindicated in patients with a known hypersensitivity to somatropin or any of its excipients. Systemic hypersensitivity reactions have been reported.

**Diabetic Retinopathy:** Somatropin is contraindicated in patients with active proliferative or severe non-proliferative diabetic retinopathy.

Please see additional Important Safety Information on the next page and visit [Serostim.com/PI](http://Serostim.com/PI) for full Prescribing Information.



The Patient AXIS Center® is a patient support program dedicated to Serostim® reimbursement and education. To learn more about how the Patient AXIS Center® provides eligible patients with a variety of product support benefits or to schedule injection training, please call the Patient AXIS Center® at **1-877-714-AXIS (2947)** or visit **GetAXISupport.com**

## Serostim® (somatropin) for Injection

### IMPORTANT SAFETY INFORMATION (continued) WARNINGS AND PRECAUTIONS

**Acute Critical Illness:** Increased mortality (42% vs. 19% in somatropin compared to placebo treated) in patients with acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure has been reported after treatment with pharmacologic amounts of somatropin.

**Concomitant Antiretroviral Therapy:** Somatropin has been shown to potentiate HIV replication in vitro, and there was no increase in virus production when antiretroviral agents were added to the culture medium. No significant somatropin-associated increase in viral burden was observed. All patients received antiretroviral therapy for the duration of treatment during Serostim® clinical trials.

**Neoplasms:** Patients with preexisting tumors should be monitored for progression or reoccurrence. Monitor patients on somatropin therapy carefully for preexisting nevi.

**Impaired Glucose Tolerance/Diabetes:** Patients with other risk factors for glucose intolerance should be monitored closely during Serostim® therapy. Cases of new onset impaired glucose tolerance, new onset type 2 diabetes, and exacerbation of preexisting diabetes have been reported in patients receiving Serostim®. Some patients developed diabetic ketoacidosis and diabetic coma and, in some, improved when Serostim® was discontinued and in others persisted. Some of these patients required initiation or adjustment of antidiabetic treatment.

**Intracranial Hypertension:** Intracranial hypertension (IH) with papilledema, visual changes, headache, nausea, and/or vomiting has been reported usually within the first 8 weeks of somatropin therapy and rapidly resolved after stopping or reducing the somatropin dose. Funduscopic examination should be performed prior to initiating treatment with somatropin and periodically during treatment. If papilledema is observed, treatment should be stopped and restarted at a lower dose after IH-associated symptoms have resolved.

**Severe Hypersensitivity:** Serious systemic hypersensitivity reactions including anaphylactic reactions and angioedema have been reported with postmarketing use of somatropin products. Patients and caregivers should be informed that such reactions are possible and that prompt medical attention should be sought if an allergic reaction occurs.

**Fluid Retention/Carpal Tunnel Syndrome:** Increased tissue turgor (swelling, particularly in the hands and feet) and musculoskeletal discomfort (pain, swelling and/or stiffness) may occur during treatment with Serostim®, but may resolve spontaneously, with analgesic therapy, or after reducing the frequency of dosing. Carpal tunnel syndrome may occur and if the symptoms of carpal tunnel do not resolve by decreasing the weekly number of doses, it is recommended that Serostim® treatment be discontinued.

**Skin Atrophy:** Rotate the injection site to avoid tissue atrophy.

**Pancreatitis:** Cases of pancreatitis have been reported rarely. Consider pancreatitis in patients who develop persistent severe abdominal pain.

### ADVERSE REACTIONS

In clinical trials in HIV-associated wasting or cachexia the most common adverse reactions (incidence >5%) were arthralgia, myalgia, peripheral edema, arthrosis, nausea, paresthesia, generalized edema, gynecomastia, hypoesthesia and fatigue.

### SPECIAL POPULATIONS:

Somatropin should be used during pregnancy only if clearly needed and with caution in nursing mothers because it is not known whether somatropin is excreted in human milk. The safety and effectiveness of somatropin in pediatric patients with HIV have not been established. Clinical studies did not include sufficient numbers of subjects ≥65 to determine a response different from that of younger patients. Studies have not been conducted in patients with hepatic or renal impairment. Gender-based analysis is not available.

Please visit [Serostim.com/PI](http://Serostim.com/PI) for full Prescribing Information.



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