Serostim®
(somatropin) for injection

For your patients with HIV-associated wasting, recognize the symptoms and take action

DON'T WASTE ANOTHER MOMENT

Serostim® (somatropin) for injection is indicated for the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance. Concomitant antiretroviral therapy is necessary.

Serostim® Dosage and Administration for Treatment of HIV-associated Wasting

Serostim® is administered by subcutaneous injection (SC). The usual starting dose of Serostim® is 0.1 mg/kg once daily (up to a total dose of 6 mg). Serostim® should be administered subcutaneously once daily at bedtime according to the following body weight-based dosage recommendations:

Weight range	Dosage
>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.

Serostim® is available as 5 mg and 6 mg single dose vials and 4 mg multidose vial.

Treatment with Serostim® 0.1 mg/kg every other day was associated with fewer side effects, and resulted in a similar improvement in work output, as compared with Serostim® 0.1 mg/kg daily. Therefore, a starting dose of Serostim® 0.1 mg/kg every other day should be considered in patients at increased risk for adverse effects related to Serostim treatment (i.e., glucose intolerance).

In general, dose reductions (i.e., reducing the total daily dose or the number of doses per week) should be considered for individuals with side effects potentially related to Serostim® treatment.

In clinical trials, Serostim® provided statistically significant improvement in 3 key symptoms of HIV-associated wasting.

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 for full Prescribing Information.

AXIS CENTER®
Phone: 877-714-AXIS (2947)
FAX: 866-823-9554
GetAXISSupport.com

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

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