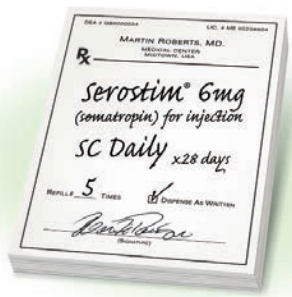
Prescribe Serostim® (somatropin) for injection today to help your patients with HIV-associated wasting

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

The usual starting dose of Serostim® is 0.1 mg/kg subcutaneously 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 BX rated, meaning no other FDA approved products are shown to be therapeutically equivalent. 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.

Only Serostim® is FDA approved to treat 3 key elements of HIV-associated wasting.

Indications and Usage

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

Important Risk Information

Contraindications

Serostim® should not be used in patients with acute critical illness, active malignancy, hypersensitivity to somatropin or any of its excipients, or diabetic retinopathy.

Increased mortality has been reported in patients with acute critical illness due to complications following surgery, multiple accidental trauma, or acute respiratory failure. Preexisting malignancies should be inactive and treatment completed prior to instituting therapy. Serostim® should be discontinued if there is evidence of tumor recurrence. Systemic hypersensitivity reactions have been reported with postmarketing use of somatropin products.

Serostim®
(somatropin) for injection
There's more to gain

See additional Important Risk Information on the back and enclosed Full Prescribing Information.

AXIS™ CENTER

Phone: 877-714-AXIS (2947)
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www.serostim.com

Body Mass Index (BMI) Table*

Height		BMI														
Feet	Inches	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
		Weight (lbs)														
4'10"	58"	67	72	76	81	86	91	96	100	105	110	115	119	124	129	134
4'11"	59"	69	74	79	84	89	94	99	104	109	114	119	124	128	133	138
5'0"	60"	72	77	82	87	92	97	102	107	112	118	123	128	133	138	143
5'1"	61"	74	79	85	90	95	100	106	111	116	122	127	132	137	143	148
5'2"	62"	76	82	87	93	98	104	109	115	120	126	131	136	142	147	153
5'3"	63"	79	85	90	96	102	107	113	118	124	130	135	141	146	152	158
5'4"	64"	81	87	93	99	105	110	116	122	128	134	140	145	151	157	163
5'5"	65"	84	90	96	102	108	114	120	126	132	138	144	150	156	162	168
5'6"	66"	87	93	99	105	112	118	124	130	136	142	148	155	161	167	173
5'7"	67"	89	96	102	108	115	121	127	134	140	146	153	159	166	172	178
5'8"	68"	92	98	105	112	118	125	131	138	144	151	158	164	171	177	184
5'9"	69"	95	101	108	115	122	128	135	142	149	155	162	169	176	182	189
5'10"	70"	97	104	111	118	126	132	139	146	153	160	167	174	181	188	195
5'11"	71"	100	107	114	122	129	136	143	150	157	165	172	179	186	193	200
6'0"	72"	103	110	118	125	132	140	147	154	162	169	177	184	191	199	206
6'1"	73"	106	113	121	129	136	144	151	159	166	174	182	189	197	204	212
6'2"	74"	109	117	124	132	141	148	155	163	171	179	186	194	202	210	218
6'3"	75"	112	120	128	136	144	152	160	168	176	184	192	200	208	216	224
6'4"	76"	115	123	131	139	148	156	164	172	180	189	197	205	213	221	230
6'5"	77"	118	126	135	143	151	160	168	176	185	193	202	210	218	227	235
6'6"	78"	121	130	138	147	155	164	172	181	190	198	207	216	224	233	241

*Source: NIH/National Heart, Lung and Blood Institute (NHLBI)

This BMI chart is provided as a reference to determine a patient's weight category and should not be used for dosing.

ADDITIONAL IMPORTANT RISK INFORMATION

Warnings and Precautions

- **Acute Critical Illness:** Increased mortality 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 somatropin.
- **Concomitant Antiretroviral Therapy:** Somatropin has been shown to potentiate HIV replication in vitro, however there was no increase in virus production when antiretroviral agents were added to the culture medium. All patients received antiretroviral therapy for the duration of treatment during Serostim® clinical trials and no significant increase in viral burden was observed.
- **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:** 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. Patients with risk factors for hyperglycemia and glucose intolerance should be monitored closely.
- **Intracranial Hypertension:** Intracranial hypertension (IH) with papilledema, visual changes, headache, nausea, and/or vomiting has been reported. Funduscopic examination should be performed prior to initiating treatment with Serostim® and periodically during the course of 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:** Swelling (particularly in the hands and feet), musculoskeletal discomfort, or carpal tunnel syndrome may occur during treatment with Serostim®. Symptoms may resolve spontaneously, with analgesic therapy, or after reducing the frequency of dosing. If 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 >10%) were increased tissue turgor, arthralgia, myalgia, and arthrosis. Other common adverse reactions (incidence >5%) included nausea, fatigue, gynecomastia, paresthesia, and hypoesthesia.

Use in 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 patients with hepatic or renal impairment or in patients aged 65 years and over have not been evaluated in clinical studies.

Please see the full prescribing information enclosed for a complete discussion of Serostim® risks.

EMD Serono

EMD Serono is a business of Merck KGaA, Darmstadt, Germany

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