INDICATIONS AND USAGE
Serostim® [somatropin (rDNA origin) 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.

CONTRAINDICATIONS
Acute Critical Illness: Growth hormone therapy 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: In general, 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. Somatropin should be discontinued if there is evidence of recurrent activity.

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

Hypersensitivity: Serostim® is contraindicated in patients with a known hypersensitivity to somatropin or diluent.

See additional Important Risk Information on the following pages and enclosed Full Prescribing Information.
In a 12-week double-blind placebo-controlled study, followed by a 12-week open-label extension phase, Serostim® increased lean body mass and weight.

Increases in lean body mass were maintained or improved through 24 weeks. Increases in weight were maintained through 24 weeks.

In clinical trials, patients with HIV-associated wasting taking Serostim® showed statistically and clinically significant improvement in physical endurance and increases in lean body mass and weight.

Serostim® significantly improved physical endurance for patients, as assessed by a stationary bike exercise in a 12-week clinical study.

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

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In newly diagnosed HIV positive patients on antiretroviral therapy to long-term survivors, unintentional weight loss remains a concern.1,8 Speaking with your patients living with HIV can help reveal decreased physical endurance and loss of lean body mass and weight resulting from HIV-associated wasting.

Questions you can ask to begin the conversation may include:

- Are any activities more difficult to perform?
- Are you exercising less?
- Do you need to rest more often?
- Do you frequently feel tired after certain activities?
- Have you recently lost weight without trying?
- Do any changes in your weight negatively affect your health and how you feel?
- Do your clothes fit more loosely than normal due to unintentional weight loss?
- Have friends, family, or coworkers noticed any changes in the way you look based on changes in your weight?
Important Risk Information, continued.

**Intracranial Hypertension:** Intracranial hypertension (IH) with papilledema, visual changes, headache, nausea, and/or vomiting has been reported in a small number of patients treated with somatropin products. Symptoms usually occurred within the first eight (8) weeks after the initiation of somatropin therapy. In all reported cases, IH-associated signs and symptoms rapidly resolved after cessation of therapy or a reduction of the somatropin dose. Funduscopic examination should be performed routinely before initiating treatment with somatropin to exclude preexisting papilledema, and periodically during the course of somatropin therapy. If papilledema is observed by funduscopy during somatropin treatment, treatment should be stopped. If somatropin-induced IH is diagnosed, treatment with somatropin can be restarted at a lower dose after IH-associated signs and symptoms have resolved.

**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 during treatment with Serostim®. If the symptoms of carpal tunnel syndrome do not resolve by decreasing the weekly number of doses of Serostim®, it is recommended that treatment be discontinued.

**Local and Systemic Reaction:** Injection site should be rotated to avoid tissue atrophy. Patient should be informed that such reactions are possible and that prompt medical attention should be sought if allergic reactions occur.

**Neoplasms:** Because malignancies are more common in HIV positive individuals, the risks and benefits of starting somatropin in HIV positive patients should be carefully considered before initiating Serostim® treatment and patients should be monitored carefully for the development of neoplasms if treatment with somatropin is initiated.

Monitor all patients with a history of any neoplasm routinely while on somatropin therapy for progression or recurrence of the tumor and for increased growth, or potential malignant changes of preexisting nevi.

**Pancreatitis:** Cases of pancreatitis have been reported rarely in adults. Pancreatitis should be considered in any somatropin-treated patient who develops abdominal pain.

### ADVERSE REACTIONS

In clinical trials in HIV-associated wasting or cachexia the most common adverse reactions included (incidence >10%) peripheral edema and musculoskeletal disorders (arthralgia, myalgia, arthrosis).

#### CONTROLED CLINICAL TRIAL 2 ADVERSE REACTIONS OCCURRING IN AT LEAST 5% OF PATIENTS IN 1 OF THE TREATMENT GROUPS AND AT AN INCIDENCE GREATER THAN PLACEBO

<table>
<thead>
<tr>
<th>Body System Preferred Term</th>
<th>Placebo (%)</th>
<th>0.1 mg/kg every other day Serostim® (%)</th>
<th>0.1 mg/kg daily Serostim® (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Musculoskeletal System Disorders</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arthralgia</td>
<td>11.3</td>
<td>24.5</td>
<td>36.4</td>
</tr>
<tr>
<td>Myalgia</td>
<td>11.7</td>
<td>17.9</td>
<td>30.4</td>
</tr>
<tr>
<td>Arthrosis</td>
<td>3.6</td>
<td>7.8</td>
<td>10.7</td>
</tr>
<tr>
<td><strong>Gastrointestinal System Disorders</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>4.9</td>
<td>5.4</td>
<td>9.1</td>
</tr>
<tr>
<td><strong>Body As A Whole - General Disorders</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Edema Peripheral</td>
<td>2.8</td>
<td>11.3</td>
<td>26.1</td>
</tr>
<tr>
<td>Fatigue</td>
<td>4.5</td>
<td>3.5</td>
<td>5.1</td>
</tr>
<tr>
<td><strong>Endocrine Disorders</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gynecomastia</td>
<td>0.4</td>
<td>3.5</td>
<td>5.5</td>
</tr>
<tr>
<td><strong>Central and Peripheral Nervous System Disorders</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paresthesia</td>
<td>4.5</td>
<td>7.4</td>
<td>7.9</td>
</tr>
<tr>
<td>Hypoesthesia</td>
<td>2.4</td>
<td>1.6</td>
<td>5.1</td>
</tr>
<tr>
<td><strong>Metabolic and Nutritional Disorders</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Edema Generalized</td>
<td>1.2</td>
<td>1.2</td>
<td>5.9</td>
</tr>
</tbody>
</table>

See enclosed Full Prescribing Information


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