



If you're living with HIV and HIV-associated wasting, talk to your healthcare provider and learn if Serostim[®] is right for you.

DON'T WASTE ANOTHER MOMENT



The people in this brochure are not actual Serostim[®] patients.

Serostim[®] is the only FDA approved treatment that is proven to increase lean body mass and body weight and improve physical endurance when people living with HIV experience HIV-associated wasting.

You must be on antiretroviral therapy while taking Serostim[®].

IMPORTANT SAFETY INFORMATION

You should not take Serostim[®] if you have:

- A critical illness from surgery, serious injuries, or a severe breathing problem
- Cancer or undergoing treatment for cancer
- Eye problems caused by diabetes
- Allergies to growth hormone or other ingredients in Serostim[®] vials

Please see additional Important Safety Information inside and accompanying full Prescribing Information or at Serostim.com/PI.

HIV-associated wasting, a serious HIV-related condition, can have an effect on your body, physical endurance, and ability to complete tasks, even if your HIV is well controlled on antiretroviral therapy (ART).

People living with HIV may experience the symptoms of HIV-associated wasting, including those who:

- Are newly diagnosed
- Are Long-Term Survivors
- Have their virus well controlled on ART
- Are on ART and losing weight without trying
- Are on ART and have, or have had, an HIV/AIDS-related infection
- Are living with advanced HIV disease
- Are on ART, but their viral load has not gone down
- Have been prescribed ART but have not taken it as directed

You may experience HIV-associated wasting even when your HIV is well controlled on ART.

HIV-associated wasting is characterized by 3 key symptoms



Loss of
lean body
mass (LBM)



Loss of
body weight



Decreased
physical
endurance

HIV-ASSOCIATED WASTING SHOULD NOT BE IGNORED

HIV-associated wasting can seriously affect your health. If you are experiencing symptoms of HIV-associated wasting, talk to your healthcare provider (HCP) about whether treatment with Serostim[®] might be right for you.

Only an HCP can diagnose you with HIV-associated wasting, but first, you need to bring up your concerns.

Asking yourself these questions may help you decide if it's time to have the conversation.

- | | |
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| <input type="checkbox"/> Do I have unintentional weight loss or have I lost weight without trying? | <input type="checkbox"/> Do I have a loss of energy, along with unintentional weight loss? |
| <input type="checkbox"/> Does my unintentional weight loss affect my health? | <input type="checkbox"/> Do I frequently feel tired after certain activities? |
| <input type="checkbox"/> Do my clothes fit more loosely due to unintentional weight loss? | <input type="checkbox"/> Do I need to rest more often or am I exercising less? |
| <input type="checkbox"/> Have my friends, family, or coworkers noticed any changes in my weight? | <input type="checkbox"/> Is it more difficult to complete some of my activities? |

If you answered “yes” to any of these questions, it may be time to talk to your HCP about HIV-associated wasting.

IMPORTANT SAFETY INFORMATION (continued)

What is the most important information I need to know about Serostim[®]?

- For patients with critical illness caused by certain types of heart or stomach surgery, serious injury or a sudden and severe breathing problem, there was an increase in death in those treated with Serostim[®] compared to those patients not treated with Serostim[®] (42% vs. 19%).
- You must be on antiretroviral therapy.
- Cancer is more common in people living with HIV.
- If you have, or are at high risk for, type 2 diabetes or have higher than normal blood sugar, talk to your doctor.
- Tell your doctor if you have changes in vision, headache, nausea, and/or vomiting which may be signs of increased brain pressure.
- Seek prompt medical attention if you have an allergic reaction while taking Serostim[®].
- You may have swelling, especially in the hands and feet, as well as discomfort in bones, joints, and muscles. This may lessen with analgesics or talk to your doctor about reducing Serostim[®] dosing frequency.
- Carpal Tunnel Syndrome may occur, talk to your doctor about reducing the number of Serostim[®] doses in a week. If not resolved, treatment should be stopped.
- If you have severe abdominal pain (possibly pancreatitis), call your doctor.

In clinical trials, Serostim[®] increased LBM and body weight, and improved physical endurance

In Clinical Trial 1, Serostim[®] was studied in 178 participants diagnosed with HIV-associated wasting. 71 participants received placebo for 12 weeks and 70 received Serostim[®] daily. Some participants continued on treatment for another 12 weeks, for a total of 24 weeks.

At 12 weeks the average increase in LBM and total body weight, and average decrease in body fat were significantly greater in the Serostim[®] group compared with the placebo and participants taking Serostim[®] significantly improved their physical endurance as measured by treadmill exercise.

In Clinical Trial 2, Serostim[®] was studied in 757 participants diagnosed with HIV-associated wasting. Participants received Serostim[®] every day, or every other day, or a placebo for 12 weeks. Some participants continued on treatment to 24 weeks, and some to 48 weeks.

In Clinical Trial 2, Serostim[®] Increased LBM and Body Weight

Participants diagnosed with HIV-associated wasting and treated with Serostim[®] daily for 12 weeks experienced:



The placebo-treated group of 222 participants experienced an average **increase of 2.13 pounds (0.97 kilograms) in LBM and 1.52 pounds (0.69 kilograms) in total weight body weight**



230 participants treated with Serostim[®] every other day experienced an average **increase of 8.56 pounds (3.89 kilograms) in LBM and 4.80 pounds (2.18 kilograms) in total body weight**



218 participants treated with Serostim[®] daily experienced an average **increase of 12.85 pounds (5.84 kilograms) in LBM and 6.14 pounds (2.79 kilograms) in total body weight**

The average increases in LBM and total body weight were significantly greater in both Serostim[®] treatment groups compared to the placebo group after 12 weeks of treatment.

In Clinical Trial 2, Serostim[®] Improved Physical Endurance

Participants taking Serostim[®] significantly improved their physical endurance as measured by a stationary bike exercise after 12 weeks of treatment. On average:



222 participants who were given a placebo had an average **0.2% decrease in their physical endurance**



230 participants who received Serostim[®] every other day **increased physical endurance by 8.9%**



218 participants who received Serostim[®] daily had a **9.1% increase in physical endurance**

A total of 646 participants completed the 12-week study and continued on Serostim[®] treatment for an additional 12 weeks. 548 of these participants completed an additional 12 weeks of active treatment. Participants continuing on Serostim[®] treatment maintained or improved their physical endurance throughout the study extension period.

Patients' perceptions of the impact of 12 weeks of treatment on their wasting symptoms as assessed by the Bristol-Meyers Anorexia/Cachexia Recovery Instrument (BACRI) improved with both doses of Serostim[®] in Clinical Trial 2.

What are the most common side effects of Serostim[®] reported in clinical trials in patients treated for HIV-associated wasting or cachexia?

- Swelling, especially in the hands or feet or around the eyes
- Bone, muscle, and joint pain or stiffness
- Tingling, numbness and pain in the fingers, thumb or wrist
- Unusual skin sensations
- Breast enlargement in men
- Nausea
- Extreme tiredness

Please see Important Safety Information throughout and accompanying full Prescribing Information or at Serostim.com/PI.


Serostim[®]
(somatropin) for injection



For more information about Serostim®, visit Serostim.com



The **AXIS Center®** is a program that provides eligible patients prescribed Serostim® with a variety of support services, including:



A dedicated case manager



Financial assistance programs



Injection training



Product Support Specialists



If you've been prescribed Serostim®, call the **AXIS Center®** at **1-877-714-AXIS (2947)** to start getting treatment support today.

Other less common but serious side effects of Serostim® are:

- High blood sugar (hyperglycemia/diabetes) which can include symptoms of increased thirst and urination, tiredness, or trouble concentrating.
- Headaches, changes in vision, nausea or vomiting, which require immediate medical attention.
- Serious allergic reactions that require immediate medical attention.
- Pain and tenderness in the abdomen.

These are not all the possible side effects. Let your doctor know about any side effects you experience. Talk to your doctor or pharmacist about the following before taking Serostim®

- If you are taking any other medicines (prescription or over the counter), vitamins, or supplements as these may affect each other. Your doctor may need to adjust the dose of Serostim® or other medicines you are taking.
- Serostim® should be used during pregnancy only if clearly needed.
- Caution should be used in nursing mothers as it is unknown if Serostim® is passed in human milk.
- Safety and effectiveness in pediatric HIV patients have not been established.
- Unknown if HIV patients ≥ 65 years of age have a different response to Serostim® than those < 65 years of age.

How should you administer Serostim®?

Patients and caregivers should be trained by a healthcare professional on how to mix and inject Serostim® prior to use. Never share Serostim® with another person, even if the needle is changed. Injection sites can include arms, legs, abdomen and should be changed daily to avoid injecting Serostim® in areas that are sore or bruised.

You are encouraged to report possible side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You can also contact EMD Serono at 1-800-283-8088 ext. 5563

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