

HIV-ASSOCIATED WASTING DISCUSSION GUIDE

PREPARING TO DISCUSS HIV-ASSOCIATED WASTING WITH YOUR HCP

For people living with HIV, losing lean body mass and body weight and experiencing reduced physical endurance may be associated with HIV-associated wasting. This HIV-related condition can have an effect on your body, physical endurance and ability to complete tasks, even if you are undetectable.

If you think you are experiencing HIV-associated wasting, it is important to discuss your symptoms and concerns with your healthcare provider (HCP). Be sure to talk to your HCP about the potential benefits and risks of treatment with Serostim[®].

Here are some conversation starters that can help you begin a discussion with your HCP. You can take the first step by bringing it up at your next visit.

COULD I HAVE HIV-ASSOCIATED WASTING?

- I have lost weight recently without trying. Could I have HIV-associated wasting?
- My friends and family have noticed changes in my weight. Could I have HIV-associated wasting?
- I have less energy and I have lost weight. Could this be a sign of HIV-associated wasting?
- My unintentional weight loss is affecting my health. Is this a symptom of HIV-associated wasting?

CAN WE DISCUSS ADDRESSING IT?

- I've been experiencing unintentional weight loss. I've tried changing my diet, but I haven't seen results. And my physical endurance is still low. Is there anything else I can try?
- I'd like to discuss some HIV-associated wasting symptoms I am experiencing. Is there anything that can treat it?
- I haven't been able to gain back weight or keep weight on. How can this be addressed?
- I have been reading about Serostim[®]. Can we discuss whether it may be an option for me?

What is Serostim[®] (somatropin) for injection?

Serostim[®] is an injectable prescription medicine used for the treatment of HIV-positive patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance. Treatment with antiretroviral therapy at the same time is necessary.

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

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.

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



HERE'S HOW I'M TRACKING

If you have been experiencing unintentional weight loss and a decrease in physical endurance, you can use this tracker to keep a record of your weight, your physical endurance, and other helpful information you can review with your HCP at your next appointment.

INITIAL WEIGHT (this may be your pre-diagnosis weight)

_____ / _____ / _____ DATE

Keep a record of your experiences so you can share it with your HCP at your next appointment.

Date			
Weight Have you lost weight without trying?			
Nutrition Has your appetite changed? Have you made changes in your diet?			
Physical Endurance Do you need to rest more often? Is it more difficult to complete some of your activities?			

Note anything else you want to bring up at your next appointment.

IMPORTANT SAFETY INFORMATION (continued)

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 $\ensuremath{\mathsf{Serostim}}\xspace^{\$}$

 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

Please see Important Safety Information throughout this guide and visit <u>Serostim.com/PI</u> for full Prescribing Information.

