Important Risk Information, continued.

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, parasthesia, and hypotension.

SPECIAL POPULATIONS

Somatropin should be used during pregnancy only if clearly needed and reviewed. Somatropin should be used during lactation only if clearly needed. 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. Refer to the Instructions for Use for educating patients how to administer Serostim®.

References

7. Serostim® (somatropin) for injection USP Information Sheet. 2017. EMD Serono, Inc.

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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 diabietic 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.

See additional Important Risk Information on the following pages and enclosed Full Prescribing Information.
Make Serostim® (somatropin) for injection the follow-up to any conversation about decreased physical endurance and gradual, unintentional weight loss in HIV positive individuals

Only Serostim® is FDA approved to treat 3 key elements of HIV-associated wasting²

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 weight⁹,¹⁰

Serostim® significantly improved physical endurance for patients, as assessed by a stationary bike exercise in a 12-week clinical study.⁹

Only Serostim® is FDA approved to treat 3 key elements of HIV-associated wasting⁹

In a 12-week, double-blind placebo-controlled study, Serostim® increased lean body mass and weight⁹. Increases in lean body mass were maintained or improved through 24 weeks in a 12 week open label extension phase. Increases in weight were maintained through 24 weeks.¹⁰
What to expect with Serostim®

Patients with HIV-associated wasting treated with Serostim® completed the BACRI* questionnaire. Their perception of the impact of Serostim® therapy on their wasting symptoms was reported. Those treated with Serostim® reported improvements in their symptoms. After taking Serostim®, patients’ perceptions included:

- Having a better appetite
- More enjoyment in eating
- Positive changes in their appearance
- Improvements in how they felt
- That increases in weight significantly improved their health

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Serostim® should not be used in patients with acute critical illness, active malignancy, hypothyroidism, 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 institution therapy. Serostim® should be discontinued if there is evidence of tumor recurrence.

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.

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

In clinical trials in HIV-associated wasting or cachexia the most common ADVERSE REACTIONS were:

- Increased weight
- Fatigue
- Edema Generalized
- Hypertension
- Paresthesia
- Abnormalities in infection
- Nightmares
- Gynecomastia
- Ovarian cysts
- Influenza
- Hypothyroidism
- Arthrosis
- Depression
- Incontinence
- Thyrotoxicosis

Adverse reactions associated with elevated growth hormone levels are: headache, edema, nervousness, anxiety, tremor, hypomania, hypomania, hyperglycemia, hypoglycemia, hypothyroidism, thyroiditis, hyperthyroidism, and myalgia.

From newly diagnosed HIV-positive patients on antiretroviral therapy to long-term survivors, unintentional weight loss remains a concern.9,10 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 your clothes fit more loosely than normal due to unintentional weight loss?
- Have friends, family, or coworkers noticed any changes in the way that you look based on changes in your weight?

In addition to speaking with your patients, other tools that can help you screen for gradual, unintentional weight loss include measuring weight, calculating BMI, and reviewing patients on antiretroviral therapy to weight loss remains a concern.

Questions you can ask to begin the conversation may include:

- What has changed in your life that could cause a decrease in your weight?
- What has changed in your life that could cause an increase in your appetite?

Questions you can ask to begin the conversation may include:

- Have you experienced unintentional weight loss and loss of physical endurance?
- Is diet or exercise contributing to your unintentional weight loss?
- Is there an increase or decrease in your appetite?
4. Gelato M, McNurlan M, Freeland E. Role of recombinant human growth hormone and HIV-associated wasting and

References:
2. Saladri M, Schleicher R, Freeland E. Effect of recombinant human growth hormone and HIV-associated wasting and
4. Gelato M, McNurlan M, Freeland E. Role of recombinant human growth hormone and HIV-associated wasting and
6. Saladri M, Schleicher R, Freeland E. Effect of recombinant human growth hormone and HIV-associated wasting and

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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.

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