STEP BY STEP INJECTION GUIDE

Serostim® 4 mg 5 mg 6 mg
(somatropin) for injection

What is Serostim®?

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.

Read this step by step instruction guide before you begin using Serostim®. Your healthcare provider will prescribe one of three dosage strengths based on your weight: 4 mg, 5 mg, or 6 mg. They will also show you how to prepare and inject your prescription the right way.

If you cannot give yourself the injection, ask your healthcare provider or a nurse to help you, OR ask someone who has been trained by a healthcare provider or nurse to give you your injections.

The 6 mg single-dose vial is displayed below. The 5 mg and 6 mg single-dose vials come with sterile water diluent for mixing and the 4 mg multidose vial comes with bacteriostatic water diluent for mixing.

What do I need for my Serostim® injection?

A. Serostim® vial containing the medication as freeze-dried powder

B. Diluent (liquid) for mixing

C. Two needles, a longer 20-gauge needle, a shorter 29-gauge needle, one syringe*

D. Alcohol swabs to clean the vial tops and skin before injection

E. Bandage or gauze pad to cover injection site

F. Sharps container (may vary in appearance)

Note: Not all materials used for the injection may be provided by your pharmacy. Make sure all injection items are unopened prior to use. If you find an open needle or syringe packet, do not use it. Dispose of it in your sharps container. Needles and syringes should never be shared or reused. Check the expiration date and do not use if the medication is expired.

serostim.com/helpful-resources/

Sharps containers may vary in appearance.

Contents shown are not actual size and may vary in appearance.

*You may be given a different gauge needle. The longer needle is used to add diluent to the Serostim® vial and withdraw the solution before your injection, and the shorter needle is used for injection

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 back cover for continued Important Safety Information and see accompanying full Prescribing Information.

How do I inject Serostim® (somatropin)?

Before each injection, gather the materials listed on the previous page. Place them on a clean, flat surface, with good lighting. Wash your hands with soap and water before you begin. If someone else is giving you the injection, they should put on a pair of disposable gloves. The 6-mg single-dose vial is displayed in the instructions below. Throw away flip tops, alcohol swaps, and empty vials after use.

1 **Remove the flip tops** from both powder and diluent vials.

- Check the expiration date and do not use if the medication is expired

2 **Clean both rubber stoppers with a fresh alcohol swab,** then throw the swab away.

- Do not touch the vial tops with your hands or gloves after cleaning them
- If you do, wipe the tops again with a fresh alcohol swab

3 **You will use 2 needles for this process.** One to mix the dilutent and one for injection.

- You may receive the same needle size for both
- Unwrap the syringe and larger needle
- Do not touch where the needle and syringe connect
- Keeping the needle in its cap, attach it securely to the syringe

4 **Pull the syringe plunger back,** to draw in air, until it reaches the 1cc/1mL point on the syringe barrel, or to the volume indicated by your healthcare provider. (See Step 4a)

While holding the syringe in one hand

- Pull the needle cap off
- Set the needle cap aside for use later (See Step 4b)*

5 **Hold the vial of diluent.**

- Carefully insert the needle straight down through the center of the rubber stopper into the vial of diluent (See Step 5a)

Gently inject all the air from the syringe into the vial by pushing down on the plunger. (This will make it easier to withdraw the solution.) (See Step 5b)

Without removing the needle, hold the plunger with one hand and turn the vial upside down. Make sure that the needle tip is below the liquid level in the vial.

- Pull the plunger to allow the diluent to fill the syringe to the level instructed by your healthcare provider (See Step 5c.)

- Remove the needle from the vial, being careful not to touch the needle or allow it to touch any surface

6 **Hold the vial with Serostim® powder.**

- Insert the needle through the center of the rubber stopper into the vial
- Slowly and gently push the plunger, so the diluent flows down the side of the vial. Do not squirt the diluent because this will make the solution foamy
- If the solution becomes foamy, let it sit until the bubbles disappear and the liquid becomes clear
- Keeping the needle in the vial, gently swirl the vial until the powder is dissolved
- Do not shake or turn the vial upside down
- Once the medication is mixed, follow the instructions in the next steps for injection

Do not inject Serostim® if the product is cloudy immediately after reconstitution or refrigeration (with the 4-mg multidose vial only). In this case, prepare another vial and contact your healthcare provider. The solution from the single-dose 5-mg and 6-mg vials, reconstituted with Water for Injection, USP, must be used immediately. Any unused solution must be discarded. The solution from the 4-mg multidose vial, reconstituted with Bacteriostatic Water for Injection, USP, can be stored refrigerated for up to 14 days. Occasionally, after refrigeration, small colorless particles may appear in the Serostim® liquid. This is not unusual and does not prevent its use.

*If the needle and syringe come apart and they have not touched anything, simply put them back together again. If the needle or syringe has touched anything, dispose of them in your sharps container, and start over again from Step 3.

7 **Turn the vial upside down,** making sure the tip of the needle is below the liquid level.

- Slowly pull the plunger back until the syringe fills to slightly more than the unit of your prescribed dose
- Carefully remove the needle from the vial without touching the needle or allowing it to touch any surface

8 **Replace the larger needle with the smaller one.** You will inject yourself with the smaller needle.

- Take the needle cap and place it on your work surface
- Recap the needle with a scooping movement (See Step 8a)
- The cap should snap down on the needle. Do not touch the needle or allow it to touch any surface (See Step 8a)

Gently twist the needle and cap off the syringe and place them in your sharps container. (See Step 8b) Do not squirt any of the solution out of the syringe.

9 **Unwrap the second or smaller needle** and twist it onto the syringe.

- To remove any air bubbles from the syringe, hold the syringe with the needle facing straight up
- Gently tap the side of the syringe with your fingertips until the bubbles float to the top
- Gently push the plunger until a small drop of liquid appears on the top of the needle

10 **Your healthcare provider will recommend** appropriate injection sites.

- Common injection sites include: top side of the thigh, areas around the belly button, rear end, and the fleshy part of your arm
- Change the location of your injection each day so that one area does not get injected too many times in a row (See Step 10a)

- **Take an alcohol swab** and carefully clean a four-inch-square area around your injection site
- Let the skin dry (See Step 10b)

11 **Hold the syringe** in one hand and remove the cap from the needle.

- Gently pinch a three-inch fold of skin
- Point the needle downward, with the slanted, cutting edge of the needle facing up (See Step 11a)

Push the needle tip into the pinched skin as far as it will go.

- Hold the syringe steady and let go of the skin. Push the plunger down slowly and gently, as far as it will go (See Step 11b)

Pull the syringe and attached needle straight out of the skin. (See Step 11c)

12 **Clean up after injecting.** Immediately discard the injection needle, needle cap, syringe, and used gauze pads in your sharps container.

If you accidentally stick yourself with the needle, clean the stuck area carefully with soap and water to prevent infection. Then place a 2" x 2" gauze pad or bandage over the area and apply gentle pressure to stop any bleeding. If someone else gets pricked by the needle after your injection, let the area bleed freely. Then wash the area thoroughly with soap and water and call their doctor immediately to explain what happened.

How do I store Serostim® (somatropin)?

Before reconstitution:

- Keep your Serostim® vials at room temperature—between 59°F and 86°F

After reconstitution with Sterile Water for Injection, USP:

- The reconstituted solution should be used immediately and any unused portion should be discarded

After reconstitution with Bacteriostatic Water for Injection, USP (0.9% Benzyl Alcohol):

- The reconstituted solution should be stored under refrigeration (between 36°F and 46°F) for up to 14 days. Avoid freezing reconstituted vials of Serostim®

PATIENT AXIS CENTER®

Do you have questions about the injection process or your Serostim® prescription? The team of Nurse Product Specialists at the Patient AXIS Center® may be able to assist with injection training* and address your product-related questions.

Contact the Patient AXIS Center® at 877-714-AXIS (2947).

*Your healthcare provider will need to complete an injection training order.

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: certain types are 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

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

Please see accompanying full Prescribing Information.

EMD SERONO

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