



## Step By Step Injection Guide

Serostim<sup>®</sup> is injected under the skin, subcutaneously, through a short and thin needle. Depending on your weight, your doctor will prescribe one of three dosage strengths for you: 4 mg, 5 mg, or 6 mg.

Serostim<sup>®</sup> comes in packages containing vials of Serostim<sup>®</sup> powder and diluent for mixing. The 5-mg and 6-mg single-dose vials come with Sterile Water for Injection, USP; the 4-mg multidose vial comes with Bacteriostatic Water for Injection, USP.

You will also need sterile syringes and mixing needles which should be provided with your medication.

**Read this Serostim<sup>®</sup> Step By Step Injection Guide before you begin using Serostim<sup>®</sup>. A healthcare provider can show you how to prepare your injection and how to administer Serostim<sup>®</sup> the right way. Do not change your Serostim<sup>®</sup> dose unless instructed to by your healthcare provider.**

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 your injections.

**Please see Important Risk Information throughout this guide and click [here](#) or visit [Serostim.com/PI](#) for Full Prescribing Information.**

### Gather the supplies you will need to prepare Serostim<sup>®</sup> and to give your injection

The 6-mg single-dose vial is displayed in the instructions below. Please note that the characteristics of the vials you receive may vary from the images displayed in this guide.

### What do I need for my Serostim<sup>®</sup> injection?

**The Serostim<sup>®</sup> vial** containing the medication in a freeze-dried powder.

**Diluent for injection vial** holding the liquid you will mix with the Serostim<sup>®</sup> powder.

**A syringe** used to mix the diluent with the Serostim<sup>®</sup> powder.

**Two needles**, a longer, 20-gauge needle to add the diluent to the Serostim<sup>®</sup> vial and withdraw the solution prior to your injection, and a shorter, 29-gauge needle for injection.

\* You may be given a different gauge needle.

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

**A bandage or gauze pad** to cover the injection site after injection.

**Sharps container** to dispose of used needles and syringes.

**Disposable gloves** only if someone else is giving the injection.

**Note: Not all materials used for the injection are provided. 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.**

### What is Serostim<sup>®</sup> (somatropin) for injection?

Serostim<sup>®</sup> 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 RISK INFORMATION

**You should not take Serostim<sup>®</sup> 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<sup>®</sup> vials



\* Sharps containers may vary in appearance

## Injecting Serostim® (somatropin) for injection

### How do I inject Serostim®?

Before each injection, gather the materials outlined on the previous page. Place them on a clean, flat surface, in a place with good light. Make sure to wash your hands with soap and water before you begin. If someone else is giving you the injection, this person should put on a pair of disposable gloves now.

- 1 Remove the flip tops from both the drug (powder) and diluent (liquid) vials, and throw them away.**



- 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 Prepare your needle.**

Unwrap the syringe and the larger needle without touching the hub of the needle where it connects to the syringe. Remove the plastic tip protector from the syringe.

Keeping the needle in its cap, attach it securely to the syringe.



**If you touch the hub of the needle or the bottom of the syringe where the needle attaches, or if you drop the needle or syringe, dispose of them in your sharps container and use new ones.**

- 4 Prepare your syringe.**

Pull back on the syringe plunger 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 straight off with the other hand. Set the needle cap aside for use later. (See Step 4b.)

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.



### IMPORTANT RISK 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.

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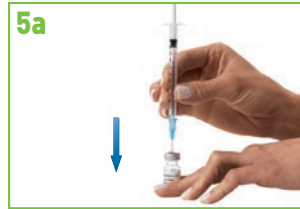
## Injecting Serostim® (somatropin) for injection (continued)

### How do I inject Serostim®? (continued)

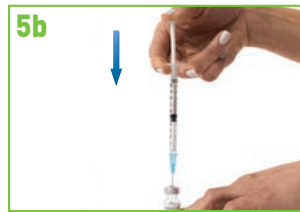
#### 5 Fill your syringe with diluent.

Place the vial of diluent on your clean work surface.

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. (The injected air 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. Pull back the syringe to make sure that the needle tip is below the diluent level in the vial. Pull the plunger to allow the diluent to fill the barrel of the syringe to the appropriate level as instructed by your healthcare provider. (See Step 5c.)



When you have the right amount of diluent in the syringe, remove the needle from the vial, being careful not to touch the needle or allow it to touch any surface.

Throw the vial of diluent away.

#### 6 Prepare your Serostim® for injection.

Place the vial containing Serostim® powder on your work surface.

Using the same syringe and needle, insert the needle through the center of the rubber stopper into the Serostim® vial. Slowly and gently push the plunger, allowing the diluent to flow down the side of the vial.



Do not squirt the diluent because this will make the solution foamy. If it 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 has been mixed, give yourself the injection as indicated in the instructions in the next steps. 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.

### IMPORTANT RISK INFORMATION (continued)

#### 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.

**Please see Important Risk Information throughout this guide and click [here](#) or visit [Serostim.com/PI](http://Serostim.com/PI) for Full Prescribing Information.**

## Injecting Serostim® (somatropin) for injection (continued)

### How do I inject Serostim®? (continued)

#### 7 Fill the syringe with the solution.

Turn the vial upside down, making sure the tip of the needle is below the fluid level.

Slowly pull the plunger back until the syringe fills to slightly more than the unit marking that corresponds to your prescribed dose.

Make sure that the tip of the needle remains in the solution while slowly backing the needle out of the vial to withdraw as much solution as possible.

Carefully remove the needle from the vial without touching the needle or allowing it to touch any surface.



#### 8 Change the needle.

Before you give yourself the injection, you must replace the larger needle with the smaller one.

Take the needle cap you set aside, place it on your work surface, and recap the needle with a scooping movement, as indicated in the photo on the right. The cap should snap down on the needle. Do not touch the needle or allow it to touch any surface. (See Step 8a.)

Once the cap is on the needle, gently twist the needle and cap off of the syringe and place them in your sharps container. (See Step 8b.)

Do not squirt any of the solution out of the syringe.



#### 9 Put on the smaller needle.

Unwrap the smaller needle and twist it onto the syringe, then carefully remove the needle cap. (See Step 9a.)

Hold the syringe straight with the needle facing up.

To remove any air from the syringe barrel and the needle, gently tap the side of the syringe with your fingertips until the bubbles float to the top of the syringe. Then gently push the plunger until a small drop of liquid appears on the tip of the needle. (See Step 9b.)



#### 10 Choose an injection site.

Your healthcare provider will recommend the appropriate injection site. Examples of common injection sites include: the top side of the thigh, the areas around the belly button, the rear end, and the fleshy part of your arm. Make sure to 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.)

Before injection, take an alcohol swab and carefully clean a four-inch-square area around your injection site. Throw the swab away and let the skin dry. (See Step 10b.)



### IMPORTANT RISK INFORMATION (continued)

**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.

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## Injecting Serostim® (somatropin) for injection (continued)

### How do I inject Serostim®? (continued)

#### 11 Inject Serostim®.

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, about an inch away from the area you plan to inject. (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.)

When the syringe is empty, pull the syringe and attached needle straight out of the skin and put it in your sharps container. (See Step 11c.)

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 patch 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.

#### 12 Clean up after injecting.

Immediately discard the injection needle, needle cap, syringe and used gauze patches in your sharps container.



## How do I store Serostim®?

### 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®.



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

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

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

### IMPORTANT RISK INFORMATION (continued)

#### 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](http://www.fda.gov/medwatch). You can also contact EMD Serono at 1-800-283-8088 ext. 5563

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