Instruction Booklet

Preparation and Administration of Octreotide Acetate for Injectable Suspension, for gluteal intramuscular use

FOR DEEP INTRAGLUTEAL INJECTION ONLY

Read this entire booklet before proceeding. If you have questions about preparation and/or administration of octreotide acetate for injectable suspension, please call 1-888-838-2872.

ATTENTION:

There are 3 critical steps in the reconstitution of octreotide acetate for injectable suspension. **Not following them could result in failure to deliver the drug appropriately.**

- **The injection kit must reach room temperature.** Remove the injection kit from the fridge and let the kit stand at room temperature for a minimum of 30 minutes before reconstitution, but do not exceed 24 hours.
- After adding the diluent solution, **ensure that the powder is fully saturated** by letting the vial stand for a minimum of 2 minutes and up to 5 minutes.
- After saturation, **shake the vial moderately in a horizontal direction for a minimum of 30 seconds,** until uniform suspension is formed.

Instructions for Gluteal Intramuscular (IM) Injection of Octreotide Acetate for Injectable Suspension

Important Information for Health Care Professionals

Successful preparation and administration of octreotide acetate for injectable suspension relies on proper suspension technique.

Follow each of the steps outlined in this instruction booklet to ensure complete saturation of the powder and its uniform suspension prior to deep intragluteal injection.

It is critical that octreotide acetate for injectable suspension and the diluent be allowed to **reach room temperature** and then be mixed **immediately** prior to injection.

Ensure that the powder is completely suspended at the time of injection.

If you have questions about preparation and/or administration of octreotide acetate for injectable suspension, please call 1-888-838-2872.

For more information on octreotide acetate for injectable suspension, see the full prescribing information.

Package Contents

- Vial containing octreotide acetate for injectable suspension
- Vial adapter for drug product reconstitution
- Prefilled syringe containing diluent
- One 1 1/2" 19-gauge safety needle

Step 1

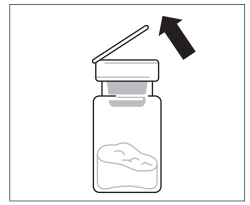
- Remove the octreotide acetate for injectable suspension kit from refrigerated storage.

ATTENTION: It is essential to start the reconstitution process only after the injection kit has reached room temperature. Let the kit stand at room temperature for a minimum of 30 minutes before reconstitution, but do not exceed 24 hours.

Note: The injection kit can be re-refrigerated if needed.

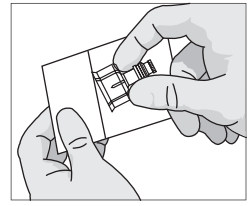
Step 2

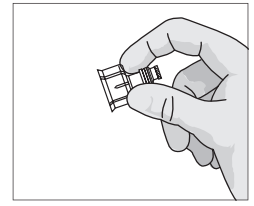
- Remove the plastic cap from the vial and clean the rubber stopper of the vial with an alcohol wipe.

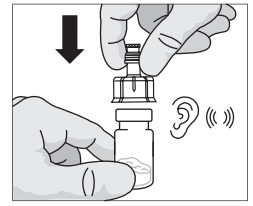


Step 3

- Peel the blister film and remove the vial adapter from its packaging by holding between the white luer cap and the skirt. **DO NOT** touch the tip of the access device at any time.
- Place the vial on a flat surface. Position the vial adapter on top of the vial and push it fully down so that it snaps in place, confirmed by an audible "click".
- **CLEAN** the tip of the vial adapter with an alcohol wipe

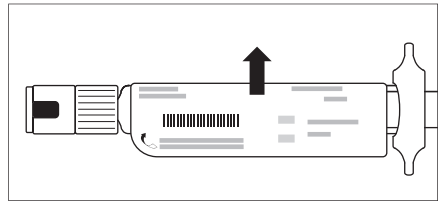






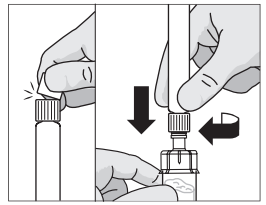
Step 4

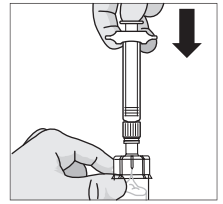
- Peel off outer syringe label.
- Inspect syringe to ensure there are no visible particles.



Step 5

- Snap off the smooth white cap from the syringe prefilled with diluent solution and screw the syringe onto the vial adapter.
- Slowly push the plunger all the way down to transfer all the diluent solution in the vial.





Step 6

ATTENTION: It is essential to let the vial stand for a minimum of 2 minutes and up to 5 minutes to ensure that the diluent has fully saturated the powder.

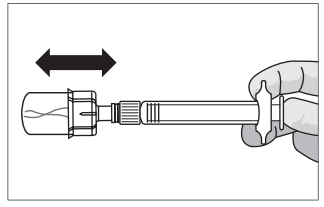
Note: It is normal if the plunger rod moves up as there might be a slight overpressure in the vial.

- **At this stage prepare the patient for injection.**

Step 7

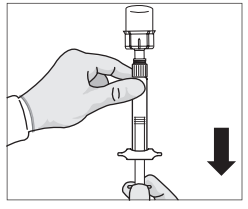
- After the saturation period, make sure that the plunger is pushed all the way down in the syringe.

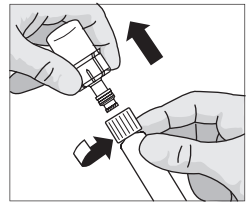
ATTENTION: Keep the plunger pressed and **shake the vial moderately in a horizontal direction for a minimum of 30 seconds** so that the powder is completely suspended (uniform milky suspension). **Repeat moderate shaking for another 30 seconds if the powder is not completely suspended.**



Step 8

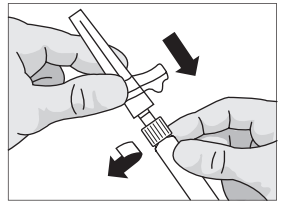
- Turn syringe and vial upside down, slowly pull the plunger back and draw the entire contents from the vial into the syringe.
- Unscrew the syringe from the vial adapter.

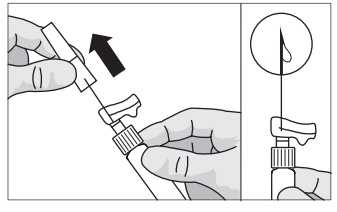




Step 9

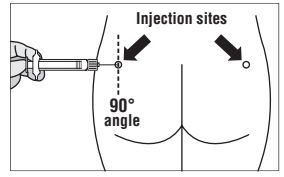
- Prepare the injection site with an alcohol wipe.
- Screw the safety injection needle onto the syringe.
- Gently **re-shake** the syringe to a milky uniform suspension.
- Pull the protective cover straight off the needle.
- Gently tap the syringe to remove any visible bubbles and expel them from the syringe.
- **Proceed immediately** to Step 10 for admininstration to the patient. **Any delay may result in sedimentation.**





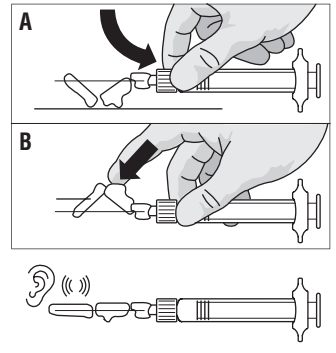
Step 10

- Octreotide acetate for injectable suspension must be given only by deep intragluteal injection, **NEVER** intravenously.
- Insert the needle fully into the left or right gluteus at a 90° angle to the skin.
- Slowly pull back the plunger to check that no blood vessel has been penetrated (reposition if a blood vessel has been penetrated).
- Depress the plunger with **steady pressure** until the syringe is empty. Withdraw the needle from the injection site and activate the safety guard (as shown in **Step 11**).



Step 11

- Activate the safety guard over the needle in one of the 2 methods shown:
  - either press the hinged section of the safety guard down onto a hard surface (figure A)
  - or push the hinge forward with your finger (figure B).
- An audible “click” confirms the proper activation.
- Note: Record injection site on patient’s record and **alternate monthly.**



Step 12

- Dispose of syringe immediately (in a sharps container).

Special precautions for disposal

- Any unused product or waste material should be disposed of in accordance with local requirements.

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