



Somatuline[®] Depot
(lanreotide) Injection

Instructions for Use – Page 1

IMPORTANT

If you have any questions about this medication or procedure, call 1-855-463-5127



Manufactured By:
Ipsen Pharma Biotech
83870 Signes FranceT

Before You Begin Injection

1. Please read both sides of these Instructions for Use before using the device. FOLLOW THIS PROCEDURE EXACTLY, AS IT MAY DIFFER FROM YOUR PAST EXPERIENCE.
2. Somatuline Depot should be administered by a Healthcare Professional.
3. If this device is dropped or damaged in any way, please call 1-855-463-5127

A. Storage of Somatuline Depot

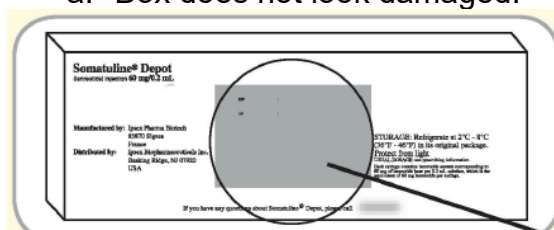
When you receive the medication, follow these steps for storing Somatuline Depot.

Important: Somatuline Depot MUST BE REFRIGERATED. DO NOT ALLOW IT TO REACH ROOM TEMPERATURE UNTIL READY TO USE.

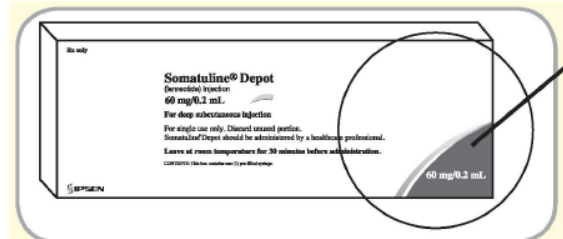
A1. Remove box from cold pack. Do not open box.

A2. Check the following:

- a. Box does not look damaged.



- b. Expiration date has not passed.



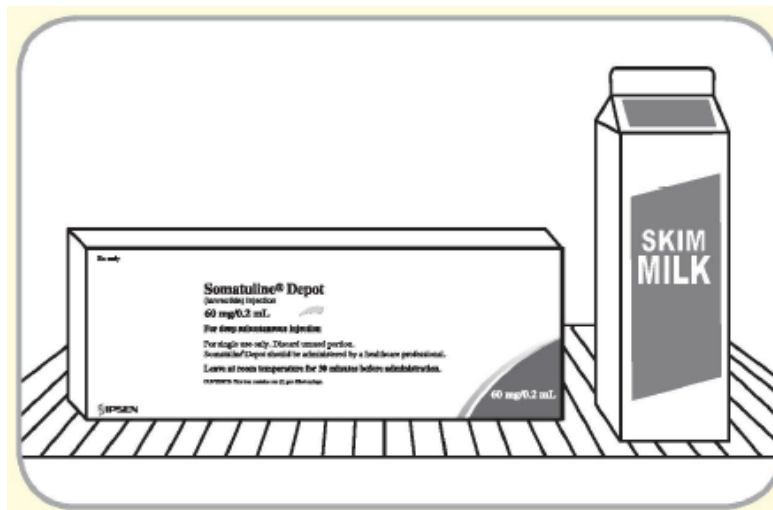
c. Dose is as prescribed.

- 60 mg, **or**
- 90 mg, **or**
- 120 mg

Note: Call 1-855-463-5127 if you have any questions.

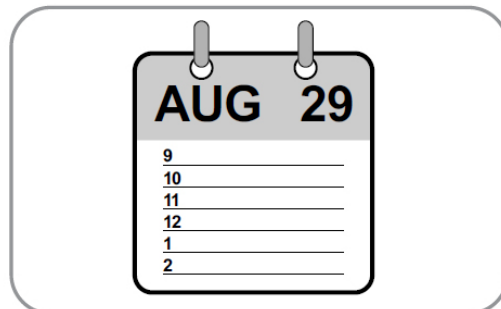
A3. Place unopened box in your refrigerator.

DO NOT PLACE IN FREEZER.



B. Prepare to Inject

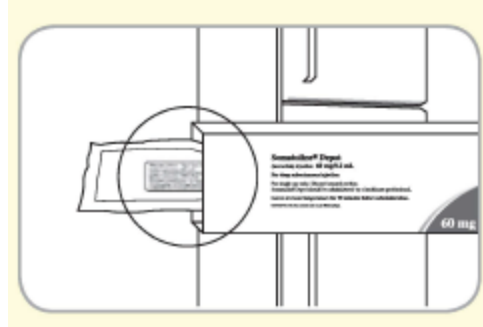
B1. Confirm that date of this injection is as prescribed.



B2. Remove box from refrigerator. Open box and remove contents.

B3. Confirm that pouch is sealed and not damaged.

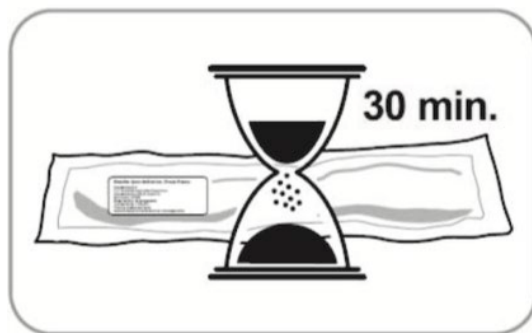
B4. Check that the dose is as prescribed and the expiration date has not passed.



B5. Let pouch sit for **30 MINUTES** to reach room temperature. **DO NOT OPEN** the pouch until ready to inject.

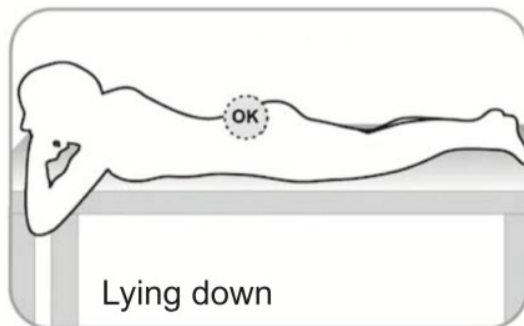
- Injection of cold medication may be painful.

Note: Product left in its sealed pouch at room temperature (not to exceed 104° F or 40 °C) for up to 72 hours may be returned to the refrigerator for continued storage and use at a later time.

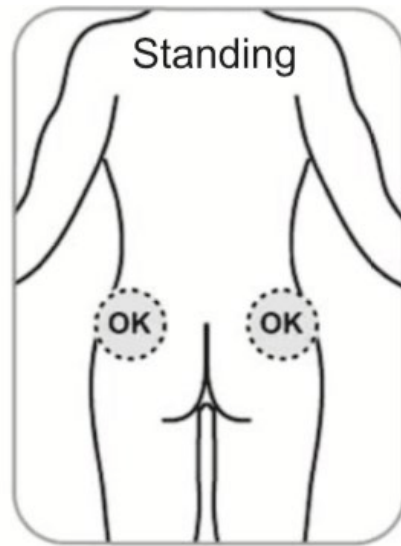


B6. Find a clean, comfortable area for the patient to relax during procedure.

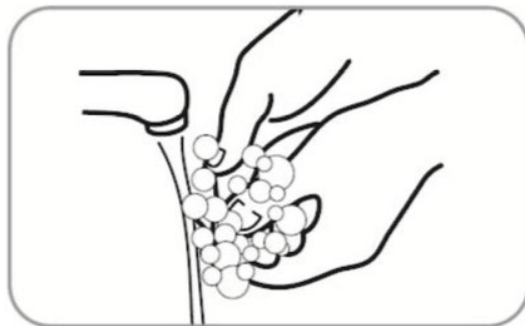
- It's important that the patient remains as still as possible during the injection.



OR

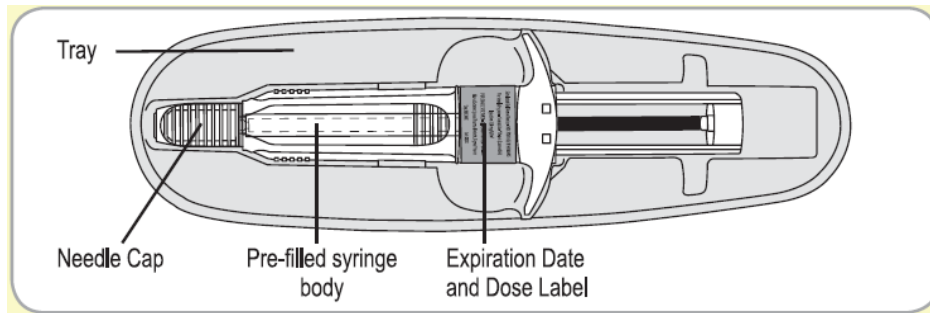


- B7.** The person administering the injection must wash his/her hands with soap and water.
Follow the doctor or institution's policy on the use of surgical gloves during this procedure.



- B8.** Tear open pouch along dotted line starting at the notch.

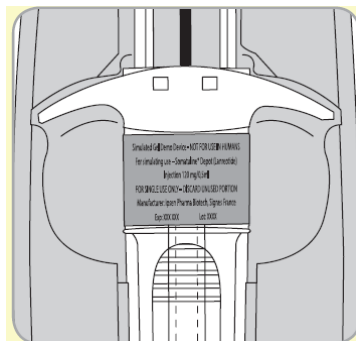




B9. Do the following:

- a. Prior to administration, inspect the SOMATULINE DEPOT syringe visually for particulate matter and discoloration. Do not administer if particulate matter or discoloration is observed. The content of the prefilled syringe is a semi-solid phase having a gel-like appearance, with viscous characteristics and a color varying from white to pale yellow. The supersaturated solution can also contain micro bubbles that can clear up during injection. These differences are normal and do not interfere with the quality of the product.
- b. Confirm that expiration date on the device has not passed.
- c. Make sure it is the right dosage:
 - 60 mg, **or**
 - 90 mg, **or**
 - 120 mg
- d. Set device aside on the empty pouch.

Note: Call 1-855-463-5127 if you have any questions.

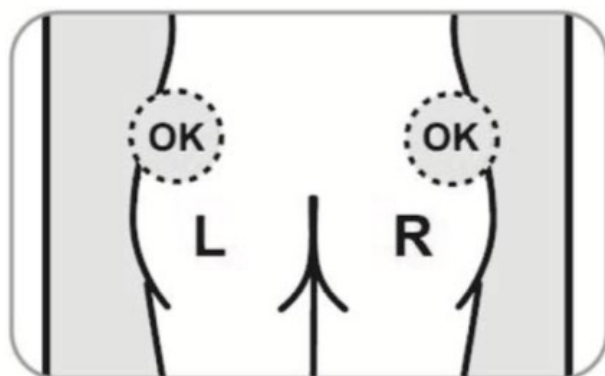


B10. Choose which side of the buttocks to inject.

- a. Switch sides with each injection.
- b. Avoid areas with moles, scare tissue, reddened skin, or skin that feels bumpy.
- c. Only inject in the areas marked with OK in the picture.

Important: It is very important that you only inject in one of the areas marked OK in the picture (upper outer quadrants of the right or left

buttocks).



B11. Clean area to be injected.



Turn page over for additional instructions



Somatuline[®] Depot
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Instructions for Use- Page 2

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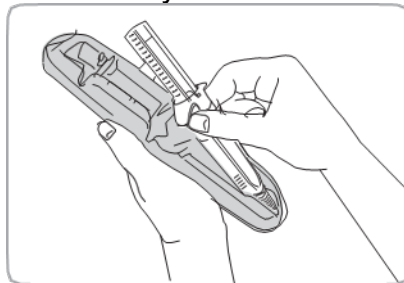
C. Inject

Important: This is a single-use pre-filled syringe with a retractable needle.

- **ALL** the medication must be injected during this use.
- If you drop or damage this device in any way, please call 1-855-463-5127

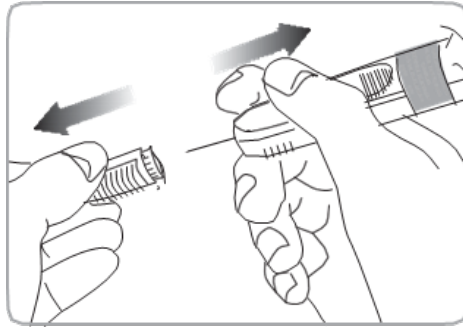
Follow these injection instructions exactly! This procedure may be different from your past experience.

- C1. BEFORE** injecting,
REMOVE the pre-filled syringe from its tray.
Discard tray.

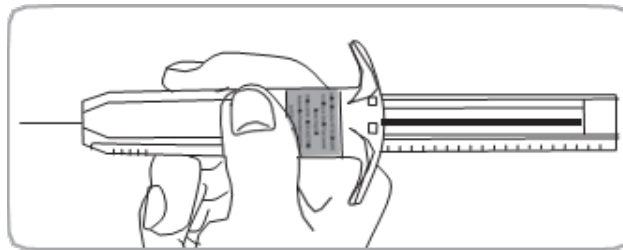


C2. REMOVE NEEDLE CAP

- **HOLD PRE-FILLED SYRINGE BY THE SYRINGE BODY** and **PULL OFF** the needle cap to remove it.
- **DO NOT HOLD** the pre-filled syringe by the plunger
- Discard needle cap.



C3. Hold pre-filled syringe by the syringe body. **The pre-filled syringe is now ready for injection.**



C4. **FLATTEN** injection area using the thumb and index finger of your other hand to stretch the skin.
• **Do NOT** pinch skin.

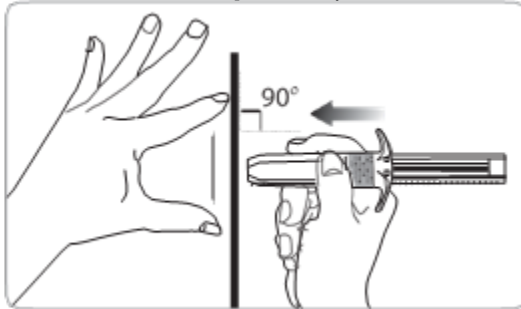


C5. Insert needle **PERPENDICULAR** to the skin (90 degree angle).

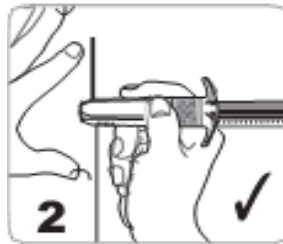
- Use a strong, straight, dart-like motion to quickly **INSERT THE**

NEEDLE ALL THE WAY INTO THE SKIN.

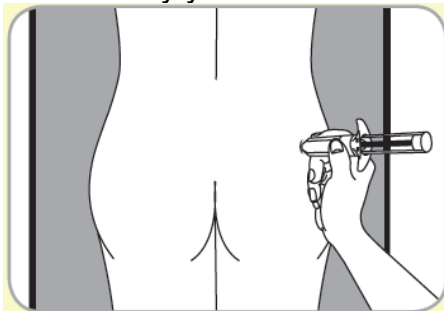
- It is very important that you insert the needle **COMPLETELY**. You should not see any needle once it is fully inserted.
- **Do not aspirate** (do not draw back).



1. Do not insert needle at an acute angle.
2. Make sure needle is fully inserted.



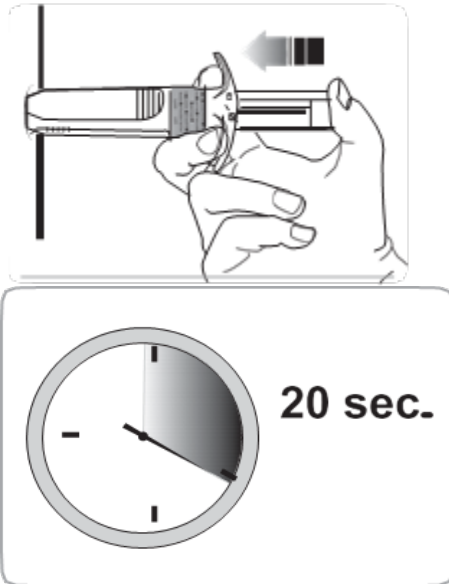
- C6.** When needle is completely inserted, release injection site that has been flattened by your hand.



- C7.** Push plunger with **STEADY, VERY FIRM PRESSURE**.

- **The medication is thicker and harder to push than you might expect.**
- While depressing plunger, slowly count to 20 and **CONTINUE STEADY PRESSURE** on the plunger. You may find it helpful to say:
 - a. "1 one-thousand"
 - b. "2 one-thousand"
 - c. "3 one-thousand" up to "20 one-thousand"

Note: Pushing the plunger too fast may cause discomfort to the patient or may break device.

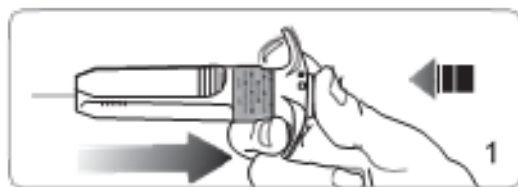


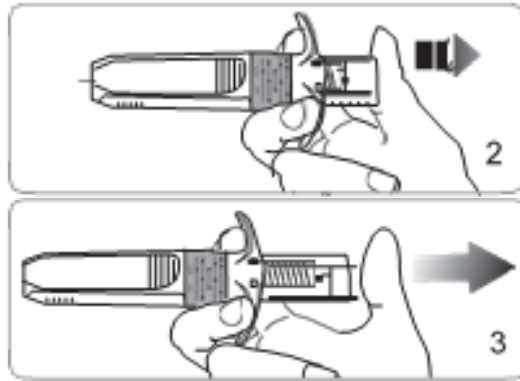
- C8. GIVE PLUNGER A FINAL PUSH** to make sure you cannot depress the plunger further.
Continue steady pressure with your thumb.



- C9.** While continuing to hold down the plunger, remove the needle from the injection site (1), then allow the needle to retract by removing your thumb from the plunger (2) (3).

- **If needle does not retract, push plunger again to engage safety mechanism. The needle will then retract.**





C10. If needed, gently apply gauze pad to injection area.

- **Important:** NEVER RUB OR MASSAGE the injection site.



D. Dispose of Pre-filled Syringe

D1. Discard used device into a hard plastic container with a screw top (such as a detergent bottle) or sharps container as per your institutional policy.



D2. Wash your hands.

