

INSTRUCTIONS FOR USE
LANREOTIDE INJECTION EXTENDED-RELEASE GEL

The following instructions explain how to inject Lanreotide Injection:

1. Read all instructions carefully before starting the injection. Follow this procedure exactly, as it may differ from your past experience.
2. This is a single-use pre-filled syringe with a single-use safety needle with a green needle shield (that cannot be removed) in a clear needle cap.
3. ALL the medication must be injected SLOWLY over 20 seconds during the use.
4. If you drop or damage the device in any way, please call 1-866-604-3268.

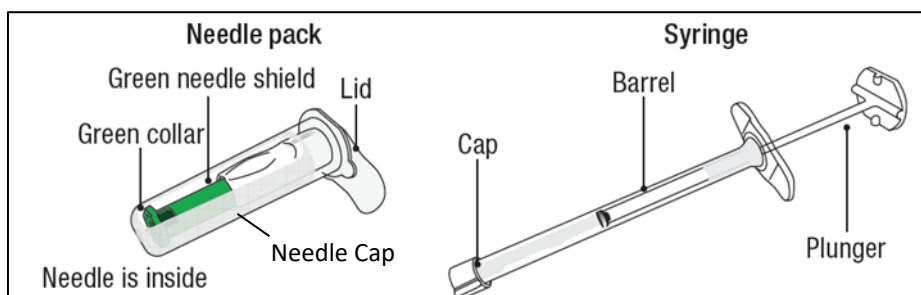
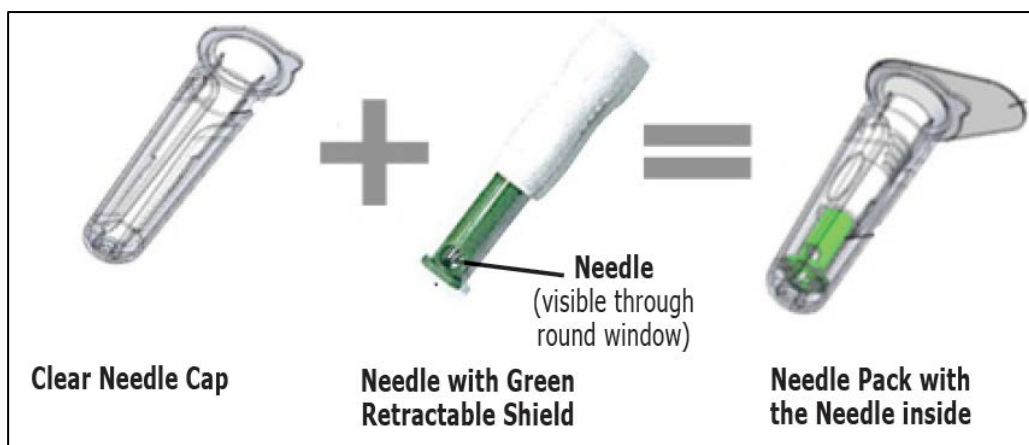


Figure 1

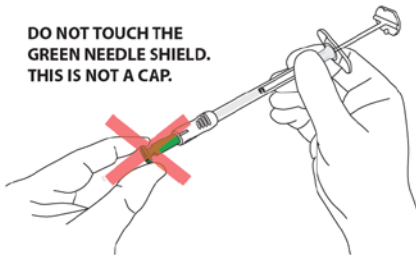
The box includes the following items:

- Sterile needle pack containing **Sterile** needle
- **Sterile** Laminated pouch with sterile syringe pre-filled with LANREOTIDE INJECTION
- Instructions for Use Leaflet
- Prescribing Information Leaflet

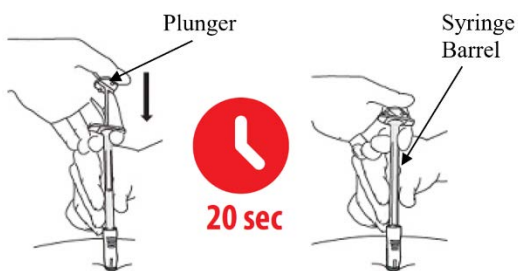


CAUTION

DO NOT TOUCH THE GREEN NEEDLE SHIELD. THIS IS NOT A CAP.



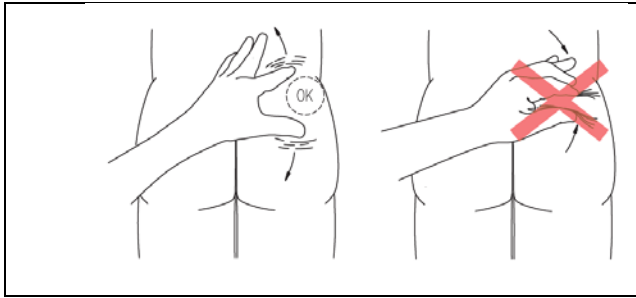
- **NEVER TOUCH OR TRY TO OPEN THE GREEN NEEDLE SHIELD** throughout the course of operation of the device.
- Green needle shield is **NOT** a removable cap or cover for the needle.
- Green needle shield will automatically activate once the injection is complete.
- Green needle shield is a self-operating safety lock mechanism.
- Needle is fully covered by green needle shield.
- Needle is visible only through a small window in the green needle shield.



- **Inject medication slowly over 20 seconds.**
- **DO NOT** rush the injection.



- Remove box from refrigerator 30 minutes prior to injecting.
- Product left in its sealed pouch at room temperature (not to exceed 104°F or 40°C) for up to 24 hours may be returned to the refrigerator for continued storage and usage at a later time.



- Stretch out the skin around injection site to make it flat and tight using your thumb and index finger.
- DO NOT pinch the skin around injection site.

A. Before you start

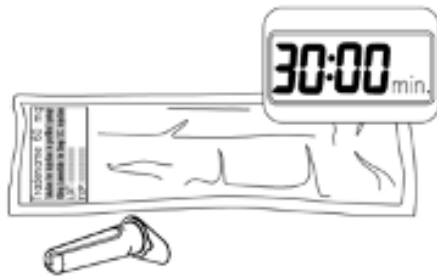


Figure 2

A1. Remove **LANREOTIDE INJECTION** from the refrigerator 30 minutes prior to injecting (**Figure 2**). Do **not** open the sterile pouch yet.

Note: Product left in its sealed pouch at room temperature (not to exceed 104° F or 40 °C) for up to 24 hours may be returned to the refrigerator for continued storage and use at a later time.



Figure 3

A2. Wash your hands with soap and dry your hands thoroughly before starting (**Figure 3**).

Follow the doctor or institution's policy on the use of surgical gloves during the procedure

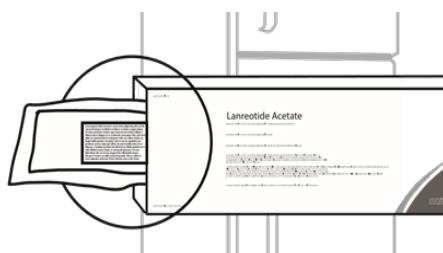
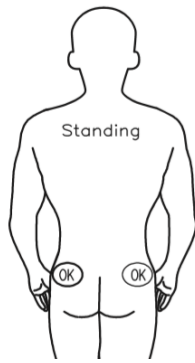


Figure 4

A3. Before opening the sterile pouch, confirm that it is intact, and that the medication has not expired. **The Syringe is sterile only if the pouch is sealed and undamaged. Do not use if the pouch is opened, tampered with or damaged.** The expiry date is printed on the outer carton and the pouch - **Do not use if the medication has expired.** (**Figure 4**).



Or



Figure 5

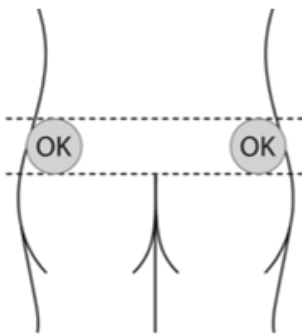


Figure 6

A4. Make sure there is a clean surface for preparation.

Find a clean, comfortable area for the patient to relax during procedure (**Figure 5**).

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

A5. Choose injection site - the sites are upper outer areas of the **buttock** as shown below
It is **very important** that you **only inject in one of the areas marked OK** in the picture (**Figure 6**).

Alternate the injection site between the right and left side each time an injection of **LANREOTIDE INJECTION** is administered.



Figure 7

A6. Prepare the injection site by cleaning it with alcohol wipes (Figure 7).

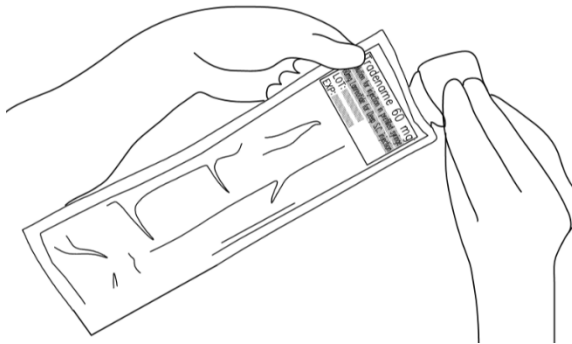


Figure 8

A7. Tear open the sterile pouch and take out the sterile pre-filled syringe (Figure 8).

B. Prepare the syringe

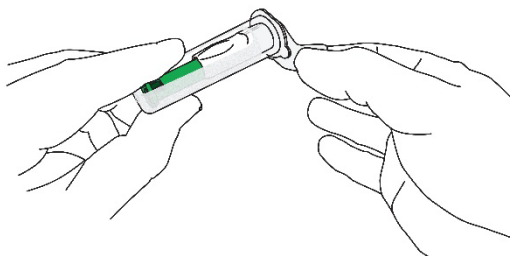


Figure 9

B1: Open the sterile needle cap (Figure 9)

- The needle is sterile only if the needle cap is sealed and undamaged. Do not use if the needle cap is opened, tampered with or damaged.
- Hold the clear needle cap and pull the lid off.
- **DO NOT TOUCH THE OPEN END OF THE NEEDLE CAP TO MAINTAIN STERILITY.**

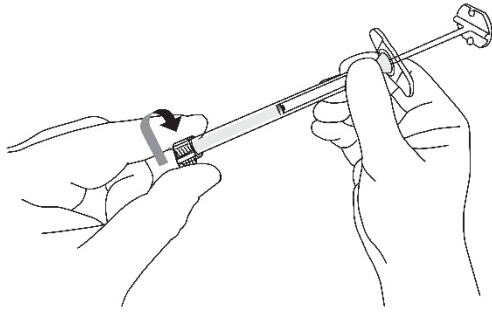


Figure 10

B2: Remove the cap from the sterile syringe (Figure 10)

- With one hand, hold the syringe barrel steady (**not the plunger**).
- With the other hand, remove the cap by twisting it.

B3: Prepare the assembly (Figure 11)

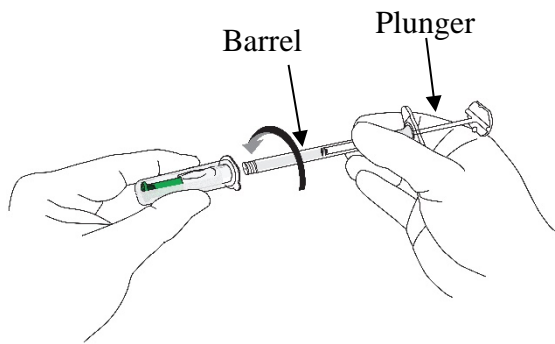


Figure 11

- Hold the needle cap with one hand and the syringe barrel (**not the plunger**) with the other
- Carefully insert the open end of the syringe into the open end of the needle cap
- Twist the syringe barrel clockwise until it is tight to make sure that the syringe is well connected to the safety needle.
- **ENSURE THAT BOTH PARTS OF THE DEVICE (SYRINGE AND NEEDLE) ARE COMPLETELY CONNECTED.**

The assembly is fully locked when you cannot turn it any further.

B4: Remove the needle from the needle cap

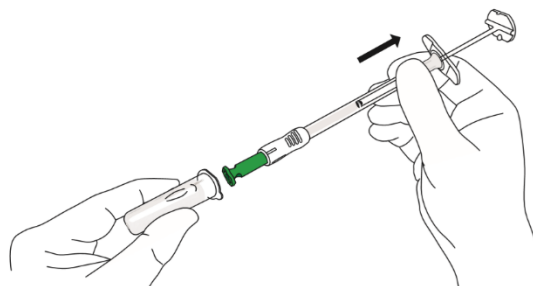


Figure 12

- Hold the syringe barrel (**not the plunger**).
- Pull the needle straight out from the needle cap **without twisting or turning (Figure 12)**.

DO NOT TOUCH THE GREEN NEEDLE SHIELD. THIS IS NOT A CAP.

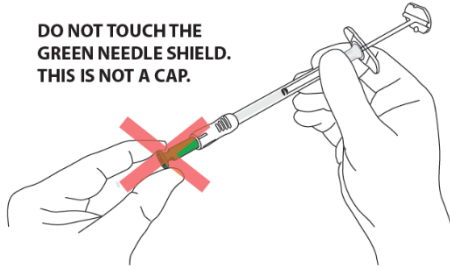


Figure 13

CAUTION: NEVER TOUCH THE GREEN NEEDLE SHIELD. THERE IS A RISK OF NEEDLE STICK INJURY. (Figure 13)

- Green needle shield is a self-operating safety lock mechanism and is not a removable cover or cap for the needle. It will activate once the injection is complete.
- The needle is fully covered by the green shield and is visible only through the small round window at the end of the shield.

C. Perform injection

C1: Position the syringe assembly



Figure 14

- Stretch out the skin around the injection site to make it flat and tight using your thumb and index finger. (Figure 14)



Figure 15

DO NOT pinch the skin (Figure 15)

ATTENTION:
90 degrees angle
is critical for proper
needle depth
to ensure deep
subcutaneous
injection

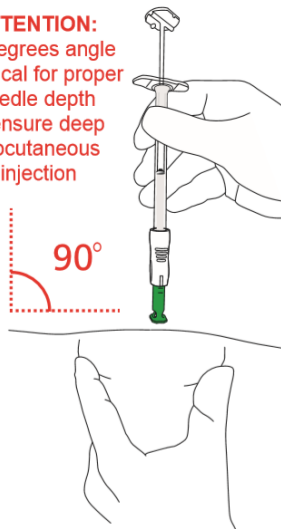


Figure 16

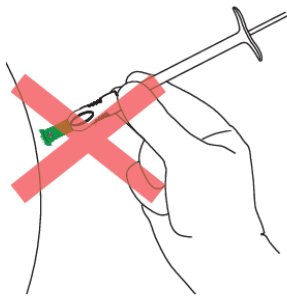
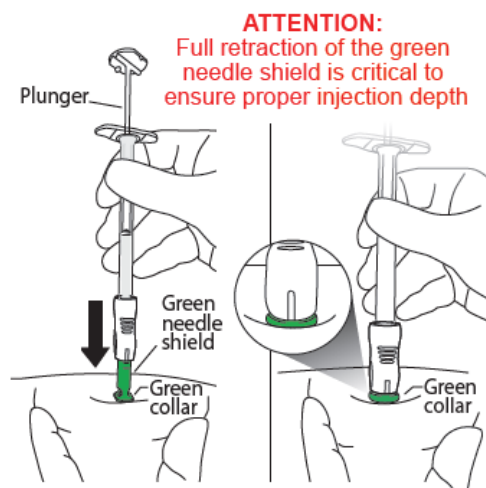


Figure 17

- Hold the assembly by the lower part of the syringe barrel (**not the plunger**) with your other hand.
- Position the syringe assembly at a **90-degree** angle to the skin. The green collar at the bottom of the green shield should be perpendicular to the injection site (**Figures 16 and 17**)

C2: Insert the needle (Figure 18)



- Holding the skin flat and tight, push the syringe assembly firmly into the skin.
- Do **NOT** pinch the skin.
- **Keep pushing until you reach a “hard stop” and only the green collar at the end of the green needle shield remains visible.**
- **Do NOT** push the plunger yet.
- **DO NOT aspirate.**
- Keep pressing against the skin.
- During this step you should not see the needle.

Figure 18

C3: Push the top of the plunger (Figure 19)

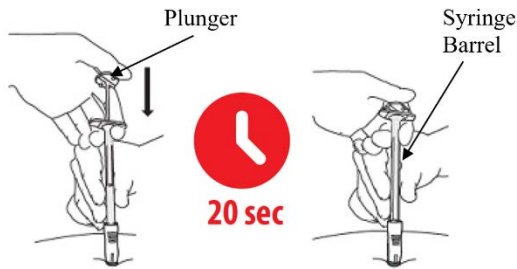
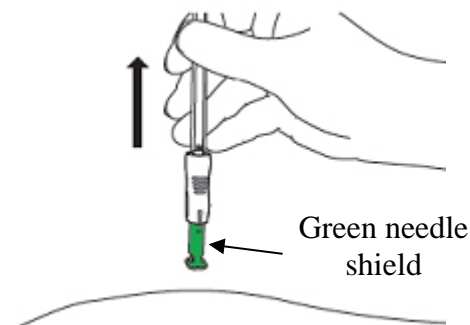


Figure 19

- Keep holding your hand on the syringe barrel to maintain a 90-degree angle throughout the injection.
- While keeping the syringe pressed against the skin, **slowly** press down the plunger. You may want to use both hands while applying pressure during the injection of drug.
- Continue slowly pushing the plunger over 20 seconds until the Plunger top touches the syringe end.
- **DO NOT** rush the injection. The medication is thicker and harder to push than you might expect. Pushing the plunger too fast may cause discomfort to the patient.
- While depressing the 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"
- During this step, as the needle is lowering, the green needle shield will retract. You should only see the green collar of the green needle shield.
- During this step you should not see the needle.

D. Remove and throw away the syringe assembly



D1: Remove from the skin (Figure 20)

- Lift the syringe straight up and away from the body.
- **The green needle shield will return to its original position and will fully cover the needle.**

Figure 20



Figure 21

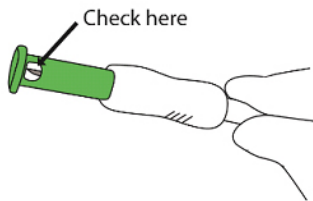


Figure 22



Figure 23

D2: Apply gentle pressure (Figure 21)

- Apply gentle pressure to the injection site with a dry cotton ball or sterile gauze to prevent any bleeding.
- **Do NOT** rub or massage the injection site after administration.

D3: Check needle (Figure 22)

- Check through the green needle shield's round windows that the needle was not damaged during administration.
- If any damage or malfunction to the needle is suspected please contact 1-866-604-3268

D4: Throw away / Disposal (Figure 23)

- DO NOT remove needle from syringe
- Dispose of complete product in sharps disposal container
- Do not dispose of the syringe or needle in the regular trash.
- The syringe and needle are not reusable.

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