

Instructions for Use
PrLUPRON DEPOT®
(leuprolide acetate for depot suspension)

Pre-filled Dual-Chamber Syringe

3.75 mg (1-Month Slow Release)
7.5 mg (1-Month Slow Release)
11.25 mg (3-Month Slow Release)
22.5 mg (3-Month Slow Release)
30 mg (4-Month Slow Release)
With Sterile Diluent

LUPRON DEPOT must be administered under the supervision of a healthcare professional. The lyophilized microspheres contained in the front chamber of the pre-filled dual-chamber syringe are to be reconstituted and administered as a single intramuscular injection as follows: 3.75 and 7.5 mg once monthly; 11.25 and 22.5 mg once every three months; 30 mg once every four months. Due to different release characteristics, a fractional dose of the 3-month or 4-month depot formulation is not equivalent to the same dose of the monthly formulation and should not be given.

The LUPRON DEPOT powder should be visually inspected, and the syringe should not be used if clumping or caking is evident. A thin layer of powder on the wall of the syringe is considered normal. The diluent should appear clear.

Follow the steps below each time you use LUPRON DEPOT

Prepare for Injection

STEP 1

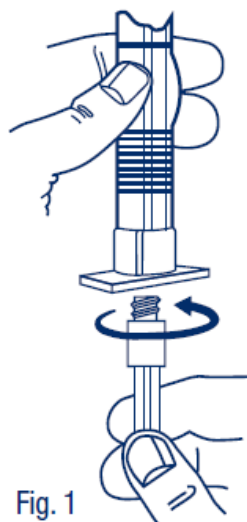


Fig. 1

- To prepare for injection, screw the white plunger into the end stopper until the stopper begins to turn (Fig. 1).
- Remember to tighten the needle by twisting the needle cap clockwise.
- Do not overtighten.

STEP 2

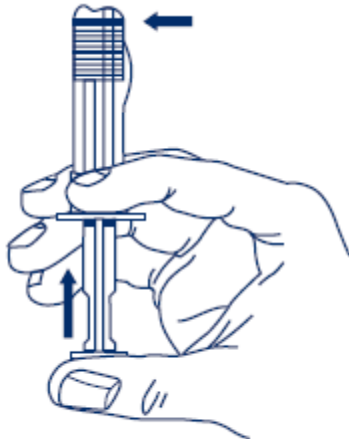


Fig. 2

Holding the syringe upright, release the diluent by **slowly pushing** (6 – 8 seconds) the plunger until the first stopper is at the **blue line** in the middle of the barrel (Fig. 2).

STEP 3

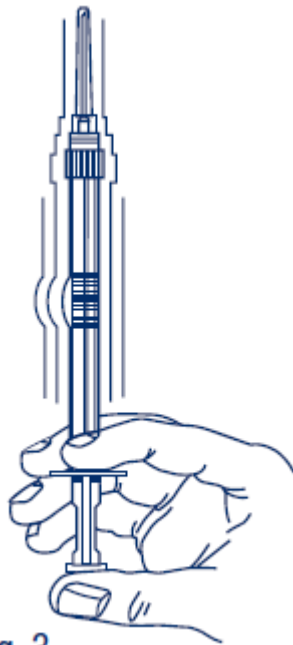


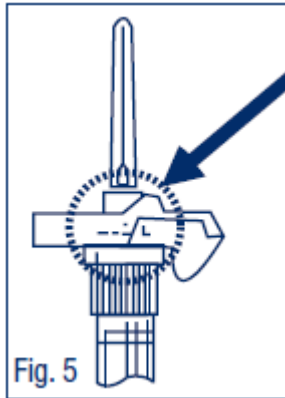
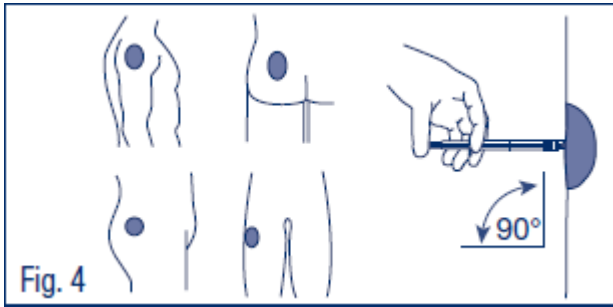
Fig. 3

- Keep the syringe upright. Gently shake the syringe to thoroughly mix the microspheres (powder) to form a uniform suspension (Fig. 3).
- The suspension will appear milky. If the microspheres adhere to the stopper or caking/clumping is present, tap the syringe against your finger to disperse.
- Do not use if any of the powder has not gone into suspension.

STEP 4

- Keep the syringe upright.
- With the opposite hand, remove the needle cap without twisting and advance the plunger to expel the air from the syringe.

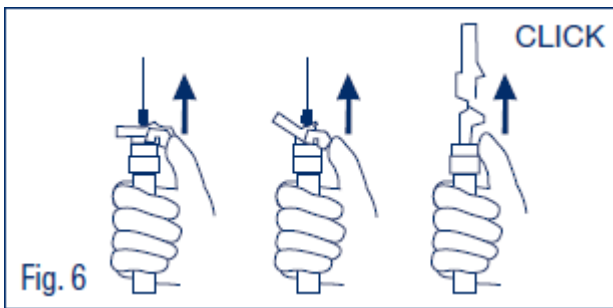
STEP 5



- At the time of reconstitution, inject the entire contents of the syringe intramuscularly by inserting the needle at a 90 degree angle into the gluteal area, anterior thigh, or deltoid; injection sites should be alternated (Fig. 4). The suspension settles very quickly following reconstitution; therefore, **LUPRON DEPOT should be mixed and used immediately.**

- **Note:** Aspirated blood would be visible just below the luer lock connection if a blood vessel is accidentally penetrated. If present, blood can be seen through the transparent LuproLoc® safety device (Fig. 5). If blood is present, remove the needle immediately. Do not inject the medication.

STEP 6



- After injection, withdraw the needle. **Immediately** activate the LuproLoc safety device by pushing the arrow forward with the thumb or finger until the device is fully extended and a **CLICK** is heard or felt (Fig. 6).

Although the suspension has been shown to be stable for 24 hours following reconstitution, since the product does not contain a preservative, the suspension should be discarded if not used immediately.

As with other drugs administered by injection, the injection site should be varied periodically.

Disposal of syringes should be done according to local regulations/procedures.

Need Help?

Please call 1-888-704-8271:

- if you have any questions regarding the drug or this procedure
- if the syringe should break or become unusable for any reason and you require a replacement

This leaflet was prepared by AbbVie Corporation.

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