LupronDepot®
(leuprolide acetate for depot suspension)

MIXING & ADMINISTERING LUPRON DEPOT

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Please see Indication and Important Safety Information on last page.

Please see full Prescribing Information or visit https://www.rxabbvie.com/pdf/lupronuro_pi.pdf.

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SYRINGE FEATURES

Use the prefilled dual-chamber syringe to mix and administer LUPRON DEPOT.

KEY FEATURES

A fine 23-gauge, 1.5" IM needle on all LUPRON DEPOT doses[2]

LuproLoc® Safety Device

Built-in safety mechanism to help prevent needlestick injuries

Prefilled Dual-Chamber Syringe[2]

No external mixing of ingredients is required

No refrigeration required[1]

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SAFETY CONSIDERATIONS[1]

Injection site reactions and injection site pain/discomfort were experienced in clinical trials.

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PREPARING FOR ADMINISTRATION

WHAT IS INCLUDED IN THIS KIT?

Your LUPRON DEPOT KIT should contain the following items:

One plunger

One prefilled dual-chamber syringe

LuproLoc® Safety Device

Two alcohol swabs

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Complete prescribing information enclosed in kit (Not displayed in this image)

You should also have a few basic supplies on hand:
gauze pads, adhesive bandages, latex or latex-free surgical gloves, and a puncture-resistant container to safely dispose of syringes and needles after use.

Store LUPRON DEPOT at room temperature

No refrigeration is required to store LUPRON DEPOT. You may store it at room temperature prior to mixing and administration. Since LUPRON DEPOT does not contain a preservative, the reconstituted suspension should be injected immediately or discarded if not used within 2 hours.[1]

Verify appropriate formulations

LUPRON DEPOT is available in different strengths and formulations. Prior to preparation for administration, please verify patient dose.

Appropriate injection sites

Before administering the intramuscular (IM) injection, assess your patient for the most appropriate injection site. As with other drugs administered by injection, the injection site should be varied periodically.[1]

Questions?

If you have any questions regarding the drug or the mixing and administration procedure, please see the accompanying full prescribing information or call 1-844-663-3742 for further assistance.

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MIXING AND ADMINISTRATION

Review these steps carefully before using Lupron. Please follow them closely to ensure proper results.

1 ASSEMBLE

a Visually inspect the LUPRON DEPOT powder
DO NOT USE the syringe if you see any clumping or caking. A thin layer of powder on the wall of the syringe is considered normal. The diluent should appear clear.[1]

b Screw plunger into end stopper
To prepare for injection, screw the white plunger into the end stopper until the stopper begins to turn.[1]

c Slowly push plunger 6-8 seconds
To help avoid needle tip leakage, hold the syringe UPRIGHT. To release the diluent, SLOWLY PUSH the plunger for 6-8 seconds until the first stopper is at the blue line in the middle of the barrel.[1] Do not pull the plunger back (or downward) at any time during the mixing process. This will help prevent stopper separation.

d Mix powder to form a uniform suspension
Keep the syringe UPRIGHT. Thoroughly mix the powder by gently shaking the syringe until the powder forms a uniform suspension. To help avoid leakage, do not shake the syringe too vigorously. The suspension should appear milky. If the powder adheres to the stopper, or if you see caking or clumping, tap the syringe with your finger to disperse. DO NOT USE the syringe if any of the powder has not gone into suspension.[1]

e Pull needle cap upward without twisting
Keep holding the syringe UPRIGHT. With your other hand, pull the needle cap upward without twisting.[1] This may help minimize the potential for product leakage.

f Advance plunger to expel air from syringe
Keeping the syringe UPRIGHT, advance the plunger to expel the air from the syringe. Now the syringe is ready for injection.[1]

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MIXING AND ADMINISTRATION (continued)

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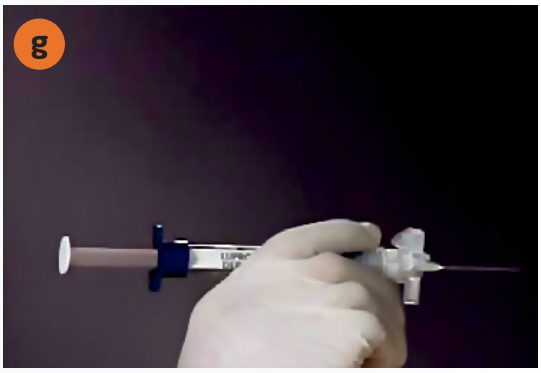
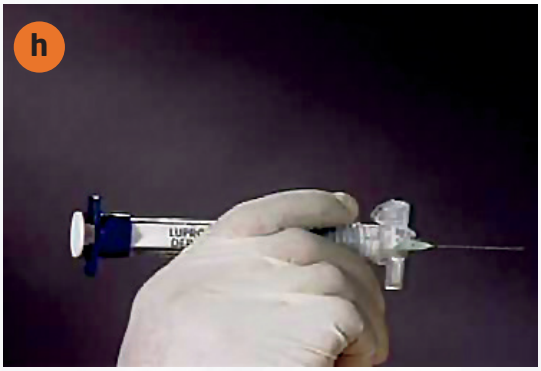
2 INJECT



g **Insert the needle at a 90-degree angle into the intramuscular injection site**

Clean the injection site with an alcohol swab and insert the needle at a 90-degree angle into the chosen intramuscular injection site. Remember: injection sites should be alternated. Note that if a blood vessel is accidentally penetrated, you may see aspirated blood just below the luer-lock connection, through the transparent LuproLoc® safety device. If this occurs, remove the needle immediately. Do not inject the medication.[1]



h **Immediately inject the contents of the syringe**

Inject the entire contents of the syringe intramuscularly immediately after reconstitution. The suspension settles very quickly following reconstitution, so LUPRON DEPOT should be mixed and used immediately.[1]

3 DISCARD

i **Withdraw the needle and activate LuproLoc**

After the injection, withdraw the needle. Immediately activate the LuproLoc safety device by pushing the arrow upward toward the needle tip with your thumb or finger until the needle cover of the safety device is fully extended over the needle and you hear or feel a click.[1] Then dispose of the syringe according to applicable regulations or procedures.

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INDICATION AND IMPORTANT SAFETY INFORMATION[1]

INDICATION

LUPRON DEPOT® (leuprolide acetate for depot suspension) 7.5 mg for 1-month, 22.5 mg for 3-month, 30 mg for 4-month, and 45 mg for 6-month administration are indicated for the treatment of advanced prostatic cancer.

IMPORTANT SAFETY INFORMATION

- LUPRON DEPOT is contraindicated in patients with hypersensitivity to GnRH agonists or any of the excipients in LUPRON DEPOT.
- LUPRON DEPOT causes an initial increase in serum testosterone (~50% above baseline) during the first few weeks of treatment. This initial increase can cause:
  - Transient worsening of symptoms, or additional signs and symptoms of prostate cancer.
  - Temporary increase in bone pain, which can be managed symptomatically.
  - Ureteral obstruction and spinal cord compression have been reported with GnRH agonists. Spinal cord compression may contribute to paralysis with or without fatal complications. Observe patients with vertebral metastasis and/or urinary tract obstruction closely.
- The use of GnRH agonists may lead to an increased risk of metabolic changes, such as hyperglycemia, diabetes, hyperlipidemia, and non-alcoholic fatty liver disease. Monitor for signs and symptoms of metabolic syndrome including lipids, blood glucose level, and/or HbA1c and manage according to current treatment guidelines.
- An increased risk of myocardial infarction, sudden cardiac death, and stroke has been reported in association with the use of GnRH agonists in men, although the risk appears low. Evaluate the risks carefully, including cardiovascular risk factors, when determining prostate cancer treatment. Patients receiving a GnRH agonist should be monitored for signs and symptoms of cardiovascular disease and managed appropriately.
- Androgen deprivation therapy (ADT) may prolong the QT/QTc interval. Consideration should be given to whether the benefits of ADT outweigh the potential risks in patients with congenital long QT syndrome, congestive heart failure, frequent electrolyte abnormalities, and in patients taking drugs known to prolong the QT interval. Correct electrolyte abnormalities and consider periodic monitoring of electrocardiograms and electrolytes.
- Postmarketing reports of convulsions have been observed in patients on leuprolide acetate therapy, including patients with a history of seizures, epilepsy, cerebrovascular disorders, central nervous system anomalies or tumors, and in patients on concomitant medications associated with convulsions, such as bupropion and SSRIs. Convulsions have also been reported in the absence of any of the conditions mentioned above.
- Periodic monitoring of serum testosterone and PSA levels is recommended.
- LUPRON DEPOT may cause fetal harm when administered to a pregnant woman. Advise pregnant patients and females of reproductive potential of the potential risk to the fetus.
- LUPRON DEPOT may impair fertility in males of reproductive potential.
- In controlled clinical trials of advanced prostatic cancer patients receiving LUPRON DEPOT, the following adverse events occurred in >10% of patients:
  - LUPRON DEPOT 7.5 mg for 1-month administration: hot flashes/sweats, general pain, edema, urinary disorders, GI disorders, and respiratory disorders.
  - LUPRON DEPOT 22.5 mg for 3-month administration: hot flashes/sweats, general pain, testicular atrophy, GI disorders, urinary disorders, injection site reactions, and joint disorders.
  - LUPRON DEPOT 30 mg for 4-month administration: hot flashes/sweats, injection site reactions, general pain, edema, urinary disorders, joint disorders, GI disorders, asthenia, flu syndrome, skin reactions, and headache.
  - LUPRON DEPOT 45 mg for 6-month administration: hot flush/flushing, upper respiratory tract infection/influenza-like illness, injection site pain/discomfort, and fatigue/lethargy.

Please see full Prescribing Information or visit https://www.rxabbvie.com/pdf/lupronuro_pi.pdf.

REFERENCES: 1. LUPRON DEPOT [package insert]. North Chicago, IL: AbbVie Inc. **2.** Data on File ABVRRTI63636.

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