LUPRON DEPOT® (leuprolide acetate for depot suspension) Important Safety Facts

Contraindications

- Patients with hypersensitivity to GnRH agonists or any of the excipients in LUPRON DEPOT.
- Women who are or may become pregnant.

Before Starting

- Hyperglycemia and increased risk of developing diabetes have been reported in men receiving GnRH agonists. Monitor blood glucose and/or glycosylated hemoglobin (HbA1c) periodically in men receiving a GnRH agonist and manage hyperglycemia or diabetes.
- 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.

What Your Patients Can Expect

- 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 in a small number of patients, which can be managed symptomatically.
  - Isolated cases of ureteral obstruction and spinal cord compression, which may contribute to paralysis with or without fatal complications. Observe patients with vertebral metastasis and/or urinary tract obstruction closely.
- Periodic monitoring of serum testosterone and PSA levels is recommended.
- LUPRON DEPOT may cause impotence.

Side Effects

- 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.

Helpful Resources

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

If your patients cannot afford their medication, contact www.pparx.org for assistance.

View the full Prescribing Information for LUPRON DEPOT at http://www.rxabbvie.com/pdf/lupronuro pi.pdf.

Indication for LUPRON DEPOT® (leuprolide acetate for depot suspension)

- LUPRON DEPOT 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 palliative treatment of advanced prostatic cancer.
- LUPRON DEPOT is a gonadotropin-releasing hormone (GnRH) agonist administered as a single intramuscular injection under the supervision of a physician.

Reference: LUPRON DEPOT 7.5 mg for 1-month, 22.5 mg for 3-month, 30 mg for 4-month, and 45 mg for 6-month [package insert].

1933586-1770907