Important Update to the Prescribing Information for LUPRON DEPOT-PED® (leuprolide acetate for depot suspension), for intramuscular use

On April 22, 2022, the Prescribing Information (PI) and Medication Guide for LUPRON DEPOT-PED update was approved as a result of the U.S. Food and Drug Administration (FDA) class safety labeling change request dated February 10, 2022. The following describes the changes in the LUPRON DEPOT-PED PI. Please refer to the full PI to review these changes.

The following information has been added in the PI:

5 WARNINGS AND PRECAUTIONS

5.4 Pseudotumor Cerebri (Idiopathic Intracranial Hypertension)

Pseudotumor cerebri (idiopathic intracranial hypertension) have been reported in pediatric patients receiving GnRH agonists, including LUPRON DEPOT-PED. Monitor patients for signs and symptoms of pseudotumor cerebri, including headache, papilledema, blurred vision, diplopia, loss of vision, pain behind the eye or pain with eye movement, tinnitus, dizziness, and nausea.

6 ADVERSE REACTIONS

6.2 Postmarketing Experience

Neurologic: pseudotumor cerebri (idiopathic intracranial hypertension)

17 PATIENT COUNSELING INFORMATION

Pseudotumor Cerebri (Idiopathic Intracranial Hypertension)

Inform patients and caregivers that reports of pseudotumor cerebri (idiopathic intracranial hypertension) have been observed in pediatric patients receiving GnRH agonists, including LUPRON DEPOT-PED. Advise patients and caregivers to monitor for headache and vision issues such as blurred vision, double vision, loss of vision, pain behind the eye or pain with eye movement, ringing in the ears, dizziness, and nausea. Advise patients and caregivers to contact their healthcare provider if the patient develops any of these symptoms *[see Warnings and Precautions (5.4)]*.

This is not a complete list of all the changes made to the Prescribing Information for LUPRON DEPOT-PED. Please refer to the full Prescribing Information for more details.

Please see Indication and additional Important Safety Information on page 2.
Please see accompanying full Prescribing Information, or visit www.rxabbvie.com/pdf/lupronpediatric.pdf

INDICATION[1]

Central Precocious Puberty

LUPRON DEPOT-PED® (leuprolide acetate for depot suspension) 7.5 mg, 11.25 mg, and 15 mg for 1-month and 11.25 mg and 30 mg for 3-month administration are indicated for the treatment of pediatric patients with central precocious puberty (CPP).

IMPORTANT SAFETY INFORMATION[1]

CONTRAINDICATIONS

- Hypersensitivity to gonadotropin-releasing hormone (GnRH), GnRH agonists, or any of the excipients in LUPRON DEPOT-PED. Anaphylactic reactions to synthetic GnRH or GnRH agonists have been reported.
- Pregnancy: LUPRON DEPOT-PED may cause fetal harm.

WARNINGS AND PRECAUTIONS

Initial Rise of Gonadotropins and Sex Steroid Levels

- During the early phase of therapy or after subsequent doses, gonadotropins and sex steroids may rise above baseline because of the initial stimulatory effect of the drug. Therefore, an increase in clinical signs and symptoms of puberty, including vaginal bleeding, may be observed during the first weeks of therapy or after subsequent doses.

Psychiatric Events

- Psychiatric events have been reported in patients taking GnRH agonists, including LUPRON DEPOT-PED. Postmarketing reports with this class of drugs include symptoms of emotional lability, such as crying, irritability, impatience, anger, and aggression. Monitor for development or worsening of psychiatric symptoms during treatment.

Convulsions

- Postmarketing reports of convulsions have been observed in patients receiving GnRH agonists, including LUPRON DEPOT-PED. These included patients with a history of seizures, epilepsy, cerebrovascular disorders, central nervous system anomalies or tumors, and patients on concomitant medications that have been associated with convulsions, such as bupropion and SSRIs. Convulsions have also been reported in patients in the absence of any of the conditions mentioned above.

Pseudotumor Cerebri (Idiopathic Intracranial Hypertension)

- Pseudotumor cerebri (idiopathic intracranial hypertension) have been reported in pediatric patients receiving GnRH agonists, including LUPRON DEPOT-PED. Monitor patients for signs and symptoms of pseudotumor cerebri, including headache, papilledema, blurred vision, diplopia, loss of vision, pain behind the eye or pain with eye movement, tinnitus, dizziness, and nausea.

ADVERSE REACTIONS

- The most common (≥2%) adverse reactions in the LUPRON DEPOT-PED clinical studies were:
  - LUPRON DEPOT-PED 7.5 mg, 11.25 mg, and 15 mg for 1-month administration: injection site reactions including abscess, emotional lability, acne/seborrhea, vaginitis/vaginal bleeding/vaginal discharge, pain, rash including erythema multiforme, headache, and vasodilation.
  - LUPRON DEPOT-PED 11.25 mg and 30 mg for 3-month administration: injection site pain, increased weight, headache, altered mood, and injection site swelling.
- Diagnostic tests of pituitary gonadotropic and gonadal functions conducted during treatment and up to 6 months after discontinuation may be affected.
- The safety and effectiveness of LUPRON DEPOT-PED have not been established in pediatric patients less than 1 year old.
- LUPRON DEPOT-PED must be administered by a healthcare professional.

Please see accompanying full Prescribing Information, or visit www.rxabbvie.com/pdf/lupronpediatric.pdf

Reference: 1. LUPRON DEPOT-PED [package insert]. North Chicago, IL: AbbVie Inc.