

## **Important Update to the Medication Guide for LUPRON DEPOT-PED® (leuprolide acetate for depot suspension), for intramuscular use**

On April 22, 2022, the LUPRON DEPOT-PED Prescribing Information and Medication Guide were updated to include new information about reports of increased pressure in the fluid around the brain in children taking gonadotropin-releasing hormone (GnRH) agonist medicines, including LUPRON DEPOT-PED, based on discussions with the United States (U.S.) Food and Drug Administration (FDA).

The following describes the recent changes to the LUPRON DEPOT-PED Medication Guide. Please refer to the full **Prescribing Information** and **Medication Guide** for additional safety information.

### **Information was added in the section “What is the most important information I should know about LUPRON DEPOT-PED?”:**

- Increased pressure in the fluid around the brain can happen in children taking gonadotropin-releasing hormone (GnRH) agonist medicines, including LUPRON DEPOT-PED. **Call your child’s doctor right away if your child has any of the following symptoms during treatment with LUPRON DEPOT-PED:**
  - Headache
  - Eye problems, including blurred vision, double vision, and decreased eyesight
  - Eye pain
  - Ringing in the ears
  - Dizziness
  - Nausea

**This is not a complete list of all the changes made to the Prescribing Information and Medication Guide for LUPRON DEPOT-PED. Please refer to the full Prescribing Information and Medication Guide to review all changes.**

## **Use for LUPRON DEPOT-PED® (leuprolide acetate for depot suspension)<sup>1</sup>**

LUPRON DEPOT-PED 7.5 mg, 11.25 mg, and 15 mg for 1-month and 11.25 mg and 30 mg for 3-month administration are prescribed for the treatment of children with central precocious puberty (CPP).

It is not known if LUPRON DEPOT-PED is safe and effective in children under 2 years of age.

## **Important Safety Information for LUPRON DEPOT-PED<sup>1</sup>**

### **What is the most important information I should know about LUPRON DEPOT-PED?**

- During the first 2 to 4 weeks of treatment, LUPRON DEPOT-PED can cause an increase in some hormones. During this time, you may notice more signs of puberty in your child, including vaginal bleeding. **Call your child's doctor if these signs continue after the second month of treatment with LUPRON DEPOT-PED.**
- Some people taking gonadotropin-releasing hormone (GnRH) agonists like LUPRON DEPOT-PED have had new or worsened mental (psychiatric) problems. Mental (psychiatric) problems may include emotional symptoms such as:
  - Crying
  - Irritability
  - Restlessness (impatience)
  - Anger
  - Acting aggressive

### **Call your child's doctor right away if your child has any new or worsening mental symptoms or problems while taking LUPRON DEPOT-PED.**

- Some people taking GnRH agonists like LUPRON DEPOT-PED have had seizures. The risk of seizures may be higher in people who:
  - Have a history of seizures
  - Have a history of epilepsy
  - Have a history of brain or brain vessel (cerebrovascular) problems or tumors
  - Are taking a medicine that has been connected to seizures, such as bupropion or selective serotonin reuptake inhibitors (SSRIs)

### **Seizures have also happened in people who have not had any of these problems. Call your child's doctor right away if your child has a seizure while taking LUPRON DEPOT-PED.**

- Increased pressure in the fluid around the brain can happen in children taking gonadotropin-releasing hormone (GnRH) agonist medicines, including LUPRON DEPOT-PED. **Call your child's doctor right away if your child develops any of the following symptoms during treatment with LUPRON DEPOT-PED:**
  - Headache
  - Eye problems, including blurred vision, double vision, and decreased eyesight
  - Eye pain
  - Ringing in the ears
  - Dizziness
  - Nausea

### **LUPRON DEPOT-PED should not be taken if your child is:**

- Allergic to GnRH, GnRH agonist medicines, or any ingredients in LUPRON DEPOT-PED. See the end of the Medication Guide for a complete list of ingredients in LUPRON DEPOT-PED.
- Pregnant or becomes pregnant. LUPRON DEPOT-PED can cause birth defects or loss of the baby. If your child becomes pregnant, call your child's doctor.

**Before your child receives LUPRON DEPOT-PED, tell their doctor about all of your child's medical conditions, including if they:**

- Have a history of mental (psychiatric) problems
- Have a history of seizures
- Have a history of epilepsy
- Have a history of brain or brain vessel (cerebrovascular) problems or tumors
- Are taking a medicine that has been connected to seizures, such as bupropion or selective serotonin reuptake inhibitors (SSRIs)
- Are breastfeeding or plan to breastfeed. It is not known if LUPRON DEPOT-PED passes into the breast milk

**Tell your child's doctor about all the medicines your child takes**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

#### **How will your child receive LUPRON DEPOT-PED?**

- Your child's doctor should do tests to make sure your child has CPP before treating them with LUPRON DEPOT-PED.
- LUPRON DEPOT-PED is given as a single-dose injection into your child's muscle each month or every 3 months by a doctor or trained nurse. Your child's doctor will decide how often your child will receive the injection.
- Keep all scheduled visits to the doctor. If a scheduled dose is missed, your child may start having signs of puberty again. The doctor will do regular exams and blood tests to check for signs of puberty.

#### **What are the possible side effects of LUPRON DEPOT-PED?**

**LUPRON DEPOT-PED may cause serious side effects. See "What is the most important information I should know about LUPRON DEPOT-PED?"**

- **The most common side effects of LUPRON DEPOT-PED received 1 time each month include:**
  - Injection site reactions such as pain, swelling, and abscess
  - Weight gain
  - Pain throughout body
  - Headache
  - Acne or red, itchy rash and white scales (seborrhea)
  - Serious skin rash (erythema multiforme)
  - Mood changes
  - Swelling of vagina (vaginitis), vaginal bleeding, and vaginal discharge
- **The most common side effects of LUPRON DEPOT-PED received every 3 months include:**
  - Injection site reactions such as pain and swelling
  - Weight gain
  - Headache
  - Mood changes

These are not all the possible side effects of LUPRON DEPOT-PED. **Call your child's doctor for medical advice about side effects.**

**This is the most important information to know about LUPRON DEPOT-PED. For more information, talk to your child's doctor or healthcare provider.**

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

**If you are having difficulty paying for your medicine, AbbVie may be able to help. Visit [AbbVie.com/myAbbVieAssist](http://AbbVie.com/myAbbVieAssist) to learn more.**

**Please see accompanying full [Prescribing Information](#), or visit [www.rxabbvie.com/pdf/lupronpediatric.pdf](http://www.rxabbvie.com/pdf/lupronpediatric.pdf)**