Important New Update to the Prescribing Information for LUPRON DEPOT-PED® (leuprolide acetate for depot suspension) Injection, Powder, Lyophilized, For Suspension

In May 2017, the LUPRON DEPOT-PED Prescribing Information (PI) was updated and key highlights are listed below. These highlights do not include all of the changes; please refer to the complete PI to review additional changes.

The following describes several of the changes in the LUPRON DEPOT-PED PI, including a new medication guide for patients.

- Under WARNINGS AND PRECAUTIONS:
  - New section was added regarding mental (psychiatric) problems that have been reported in patients taking GnRH agonists, including LUPRON DEPOT-PED. Postmarking reports with this class of drugs include emotional symptoms, such as crying, irritability, restlessness (impatience), anger, and acting aggressive. Inform your child's doctor right away if you notice any new or worsening mental symptoms or problems while taking LUPRON DEPOT-PED.
- Under ADVERSE REACTIONS:
  - New section was added under Postmarketing reports of Psychiatric Disorders: Emotional symptoms, such as crying, restlessness (impatience), anger, and acting aggressive have been observed with GnRH agonists, including LUPRON DEPOT-PED; Depression, including rare reports of suicidal ideation and attempt, has been reported with this class of drugs (GnRH agonists), including LUPRON DEPOT-PED, in children treated for Central Precocious Puberty. Many, but not all, of these patients had a history of psychiatric illness or may have had medical condition(s) that have an increased risk of depression.
- Under PATIENT COUNSELING INFORMATION:
  - A statement was added to inform and caution caregivers about psychiatric symptoms that have been observed in this drug class of therapy (GnRH agonists), including LUPRON DEPOT-PED, and to inform the child's doctor right away of any new or worsening mood symptoms during treatment with LUPRON DEPOT-PED.
  - A statement was added to inform caregivers that reports of seizures have been observed in patients receiving this drug class of therapy (GnRH agonists), including LUPRON DEPOT-PED. The risk of seizures may be higher in patients with a history of seizures, epilepsy, brain or brain vessel (cerebrovascular) problems or tumors, and in patients who are taking medications that have been associated with seizures, such as bupropion or selective serotonin reuptake inhibitors (SSRIs). Seizures have also been reported in patients without any of these conditions.
- Medication guide was added at the end of the PI. A medication guide is intended for patients to learn important information on the safe and effective use of LUPRON DEPOT-PED. Some of the possible serious side effects (such as seizures, psychiatric or mental events, and depression) are key highlights that have been included in the medication guide and are also reflected in the updated prescribing information for LUPRON DEPOT-PED. Please refer to the full PI for reference.

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.

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 (1-800-332-1088).

Click here for LUPRON DEPOT-PED full Prescribing Information.
See following pages for Use and Important Safety Information for LUPRON DEPOT-PED.

Use for LUPRON DEPOT-PED® (leuprolide acetate for depot suspension)[1]

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).

Doctors may diagnose children with CPP when signs of sexual maturity begin to develop in girls under the age of 8 or boys under the age of 9. Your doctor should perform tests to rule out possible causes of early puberty that would require different treatment (e.g., tumors).

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[1]

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 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.**

- LUPRON DEPOT-PED is injected into your child's muscle by a doctor or trained nurse.

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

- Allergic to GnRH, GnRH agonist medicines, or any 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 doctor.

Before your child receives LUPRON DEPOT-PED, tell your 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

Click here for LUPRON DEPOT-PED full Prescribing Information.

Tell your 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?

- LUPRON DEPOT-PED is injected into your child's muscle by a doctor or trained nurse.
- 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 common side effects of 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 pain
  - Weight gain
  - Headache
  - Mood changes
  - Injection site swelling

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

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 you cannot afford your medication, contact **www.pparx.org**.

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

Click here for LUPRON DEPOT-PED full Prescribing Information.

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