

## Questions for Your Child's Physician

Whether you suspect your child might be showing symptoms of central precocious puberty (CPP) or your child has already been diagnosed and you are considering treatment with LUPRON DEPOT-PED, you are sure to have questions for your child's physician. Here are some questions to start the conversation.

After you've had a chance to research the signs and symptoms of CPP and the available treatment options, be sure to add your other questions to this list. Remember, only a doctor can determine whether your child has CPP.

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

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.

### Safety Considerations

- Your child should not receive LUPRON DEPOT-PED if she/he is allergic to any of the ingredients or she is or may become pregnant.
- Increased signs and symptoms of puberty during the first few weeks of treatment may occur.
- Contact your child's healthcare provider if signs of puberty continue after the second month of treatment or if new or unusual signs or symptoms occur.
- Mental (psychiatric) problems have been reported in patients taking GnRH agonists, like LUPRON DEPOT-PED. Events include emotional symptoms such as crying, irritability, restlessness (impatience), anger, and acting aggressive.
- Inform your child's doctor right away if your child has any new or worsening mood symptoms while taking LUPRON DEPOT-PED.
- Seizures have been observed in patients taking GnRH agonists, like LUPRON DEPOT-PED, with or without a history of seizures, epilepsy, brain or brain vessel problems or tumors, and in patients taking medications that have been connected to seizures.
- Call your child's doctor right away if your child has a seizure while taking LUPRON DEPOT-PED.
- Your child's pubertal development could begin again if the injection schedule is not followed.

### QUESTIONS ABOUT CPP

- What is CPP, and what are the signs and symptoms?
- Do you see signs of CPP in my child?
- What are the long-term problems associated with CPP?
- How will you diagnose CPP?

### TREATING CPP

- What are the treatment options available?
- What are the risks and benefits of each type of treatment?
- How long will my child need treatment?
- Will you need to monitor my child during treatment? How often?
- How long will it take for my child to return to normal development?
- What happens if we don't treat this condition?

### DIAGNOSING CPP

- What tests will you use to diagnose my child?
- Does my child need all these tests?

### CHOOSING LUPRON DEPOT-PED TO TREAT CPP

- Why are you recommending (or not recommending) treatment with LUPRON DEPOT-PED?
- How does treatment with LUPRON DEPOT-PED work?
- Will the injections hurt?
- Will there be any side effects?
- What happens if we miss an injection?



Please see Use and Important Safety Information on following page.

Please see full Prescribing Information at <http://www.rxabbvie.com/pdf/lupronpediatric.pdf>.

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## Use and Important Safety Information

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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).

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### Important Safety Information for LUPRON DEPOT-PED

#### 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 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

**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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

If you cannot afford your medication, contact [www.pparx.org](http://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.**