

MEDICATION GUIDE
LUPRON DEPOT-PED® (loo-pron depo peed)
(leuprolide acetate for depot suspension)

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.**

What is LUPRON DEPOT-PED?

- LUPRON DEPOT-PED is an injectable prescription gonadotropin releasing hormone (GnRH) medicine used 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.

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 this 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 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 plans 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?

- 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 injected into your child’s muscle each month or every 3 months by a doctor or trained nurse. Your 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 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 may report side effects to FDA at 1-800-FDA-1088.**

How should I store LUPRON DEPOT-PED INJECTION?

- Store LUPRON DEPOT-PED INJECTION at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep LUPRON DEPOT-PED INJECTION and all medicines out of the reach of children.**

General information about the safe and effective use of LUPRON DEPOT-PED.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use LUPRON DEPOT-PED for a condition for which it was not prescribed.

This Medication Guide summarizes the most important information about LUPRON DEPOT-PED. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about LUPRON DEPOT-PED that is written for doctors or trained nurses.

What are the ingredients in LUPRON DEPOT-PED?

LUPRON DEPOT-PED 7.5 mg, 11.25 mg or 15 mg for 1-month administration:

Active Ingredients: leuprolide acetate for depot suspension

Inactive Ingredients: purified gelatin, DL-lactic and glycolic acids copolymer, D-mannitol, carboxymethylcellulose sodium, polysorbate 80, water for injection, USP, and glacial acetic acid, USP to control pH.

LUPRON DEPOT-PED 11.25 mg or 30 mg for 3-month administration:

Active Ingredients: leuprolide acetate for depot suspension

Inactive Ingredients: polylactic acid, D-mannitol, carboxymethylcellulose sodium, polysorbate 80, water for injection, USP, and glacial acetic acid, USP to control pH.

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For more information, go to www.lupronped.com or call 1-800-633-9110.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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