Use and Important Safety Information

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

LUPRON DEPOT-PED is not for children under 2 years of age.

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).

Important Safety Information for LUPRON DEPOT-PED

Your child should not receive any formulation of LUPRON DEPOT-PED if he/she has experienced any type of allergic reaction to LUPRON DEPOT-PED or any of its ingredients.

Your child should not receive LUPRON DEPOT-PED if he is or becomes pregnant. LUPRON DEPOT-PED can cause birth defects or loss of the baby. If your child becomes pregnant, call your doctor.

During the first few weeks of treatment, signs of puberty, such as vaginal bleeding, may occur. Call your child’s doctor if signs/symptoms of puberty continue beyond the second month of treatment.

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, epilepsy, brain or brain vessel (cerebrovascular) problems or tumors, or in people who 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.

Before your child receives LUPRON DEPOT-PED, tell your doctor about:

- All of your child’s medical conditions, including if they have any of the conditions listed above, or are breastfeeding or plan to breastfeed.
- All the medicines your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

It is important that you keep your child’s doctor appointments and follow the prescribed injection schedule. Your child may start having signs of puberty again if injections are missed. The doctor will do regular exams and blood tests to check for signs of puberty.

The most common side effects with LUPRON DEPOT-PED received 1 time each month include:

- Injection site reactions such as pain, swelling, and abscess; weight gain; pain throughout the body; headache; acne or red, itchy rash and white scales (seborrhea); serious skin rash (erythema multiforme); mood changes; and swelling of the 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, and injection site swelling. LUPRON DEPOT-PED must be administered under the supervision of a physician.

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

If your pharmacist is unable to provide these instant savings, you can still take advantage of this offer:

a. Complete this form or submit online at LupronPed.PatientSavings.com.

b. Circle the product, date, and amount you paid on the original pharmacy receipt(s) for LUPRON DEPOT-PED.

c. Mail this form, pharmacy receipt, proof of payment, and a copy of your Instant Savings Card—with the group and member numbers readable—to: LUPRON DEPOT-PED Rebate Offer, PO Box 4581, Warren, NJ 07059-0581.

In 10 to 14 days, you will receive a check for up to $250 off your 1-month prescription or $1,000 off your 3-month prescription for LUPRON DEPOT-PED.