

Facing Central Precocious Puberty

A step-by-step plan for your CPP journey



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What you need to know...



About Central Precocious Puberty (CPP)¹⁻²

CPP is when puberty starts too soon in children. The good news is CPP can be treated.

Your CPP journey³

Treatment can help slow or even stop puberty until a more appropriate age.

Resources for you

Our savings, support and free app can help you every step of the way.

Central Precocious Puberty (CPP) is a form of early puberty^{1,3-5}

Puberty normally begins in girls between the ages of 8 and 13 and in boys between the ages of 9 and 14. During puberty, the pituitary gland produces a hormone called gonadotropin-releasing hormone (GnRH).

In turn, GnRH causes increases in other hormones like luteinizing hormone (LH) and follicle-stimulating hormone (FSH).

It is these hormones that cause the ovaries to produce estrogen in girls and the testicles to produce testosterone in boys—

which lead to the changes seen during puberty. When a child shows signs of puberty too soon, it may be considered CPP.

CPP is a condition in which puberty starts too soon in children.

The cause of CPP is unknown

In most cases, there is no specific reason for your child's early development. It's not passed from parents to children, nor did you do anything to make it occur. Puberty just happens to be starting early for your child.

Understanding early puberty



Potential complications of CPP⁶

If CPP is left untreated, your child can continue to develop signs of puberty, and have lasting complications beyond childhood.

Shorter adult height

At first, early puberty may cause a child to grow much taller than other kids their age. But as bones mature, the growth plates start to close and the bones can't get any longer. This can lead to a short adult height if their CPP is not treated.

Keep in mind

Since children with CPP are often too young to understand what's happening with their bodies, it can affect how they feel and cope.

Your doctor's treatment choice²

The most common treatment for CPP is called a GnRH agonist, which is proven to help stabilize the symptoms of CPP. It works by blocking the release of sex hormones in the body. In other words, it tells the pituitary gland to ignore GnRH signals. This causes the ovaries or testes to stop making sex hormones and helps delay the physical changes of puberty.

Treating with LUPRON DEPOT-PED® (leuprolide acetate for depot suspension)⁷

Since 1993 doctors have prescribed LUPRON DEPOT-PED more than any other CPP treatment.*

As a GnRH agonist, LUPRON DEPOT-PED works by interrupting the release of puberty-causing hormones until it is a more appropriate time for puberty to occur.



prescribed treatment for CPP

With LUPRON DEPOT-PED, your doctor can create a treatment plan specific to your child's needs so he or she gets the right amount of medicine for the right number of months.



Please see Use and Important Safety Information on page 15.
Please see accompanying full Prescribing Information.

#1 prescribed treatment for CPP

#1



- 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.

*Based on IMS Health, DDD™, and NDCHealth®, NDC Non-Retail™

At the doctor's office...⁷

LUPRON DEPOT-PED (leuprolide acetate for depot suspension) is given as an injection in your doctor's office. Your pediatric endocrinologist will want to monitor your child at least 4 times per year.

At home...

Since you know your child better than anyone, your doctor may ask about any observations you make between appointments, such as how your child is reacting to therapy.



From your child...⁶

It can be confusing and embarrassing to develop much earlier than friends who are the same age. Let your child know that all kids change due to puberty, but his or her changes are just occurring earlier than usual. And even though these changes are normal, he or she will be taking medicine on a regular basis to slow them down. Encourage your child to continue doing activities that he or she enjoys.

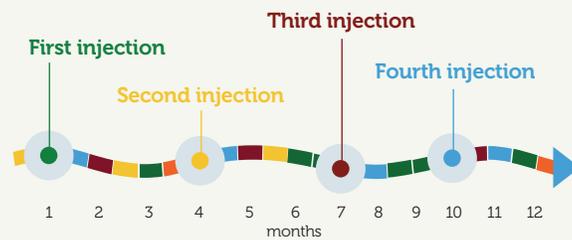
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What to expect



From treatment...?

3-month dosing—4 injections per year



With 3-month dosing, your child will get 4 injections per year. Your regularly scheduled doctor visits will coincide with your child's injections, so they fit your schedule.

Having 4 visits a year also gives your doctor every chance to monitor your child's CPP treatment along the way and make any adjustments that may be needed.



LUPRON DEPOT-PED (leuprolide acetate for depot suspension) is the only GnRH that has a long-term study⁷

An 18-year study of the LUPRON DEPOT-PED 1-month formulation was conducted to examine the long-term impact on growth patterns and reproductive function of children treated for CPP.

During the first 5 years of treatment, the clinical signs of puberty were stopped in most children. Average growth rates decreased as well.



In about 88% of children, hormones returned to pubertal levels by 6 months after stopping treatment.

Patients who were treated with LUPRON DEPOT-PED and then followed until they reached adulthood, on average, were taller than the height that was predicted for them after they were initially diagnosed with CPP.



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In the future...



The average age after stopping treatment when girls started getting menstrual periods (or restarted, if they had already had them) was 12.9 years.



Some patients who were treated with LUPRON DEPOT-PED, and then followed until they reached adulthood, reported pregnancies. Twelve pregnancies were reported in a post-treatment survey, including multiple pregnancies in 4 women.

Things To Keep In Mind

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.

Your child's pubertal development could begin again if the injection schedule is not followed.

Every child is unique – how your child's symptoms progress and how he or she responds to treatment may be different than in other children.



Regular visits allow the doctor to monitor your child's progress and adjust the dosage if needed, so it's important to keep all your appointments.



Plan. Monitor. Track.

Only LUPRON DEPOT-PED offers the support of an app, CPP Tracker, so you can keep track of your child's doctor appointments and progress right on your smartphone.

CPP Tracker can help you simplify monitoring treatment with LUPRON DEPOT-PED. This free and simple iPhone® app allows you to stay on top of your child's CPP journey anywhere you go.



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Monitor and track



CPP Tracker features:

- Appointment reminders linked to your smartphone calendar
- Timely questions for your doctor
- Space to make observations and record measurements
- What to expect from therapy
- Nurse Hotline connection
- Links to informational websites



Talk to your doctor today about treating your child's CPP with LUPRON DEPOT-PED (leuprolide acetate for depot suspension).



CPP Tracker

Get instant savings

With LUPRON DEPOT-PED, you are not alone on your CPP journey. We are here to support you and your child every step of the way—answering your questions and offering guidance. We may also be able to help you save money on every prescription.



LUPRON DEPOT-PED Instant Savings Card

Save up to \$2,000 per year on your prescription for any LUPRON DEPOT-PED formulation.

- For 1-Month (monthly) dosing: Save up to \$150 off each prescription after \$10 co-pay expense*
- For 3-Month dosing: Save up to \$1,000 off each prescription after \$10 co-pay expense*

*For full details and eligibility requirements, please visit

www.lupronped.com/support-savings/savings

For more information visit
www.lupronped.com

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Support PLUS



Complimentary live nurse support

Connect to our certified nurses who can answer your questions about CPP and treatment while your child is on therapy with LUPRON DEPOT-PED.



1-855-LUPRON-P
(1-855-587-7667)

Monday-Saturday 10am-7pm CST

Can't afford your medicine?

We can help. If you don't have prescription drug coverage and cannot afford your medication, the Partnership for Prescription Assistance can help qualified patients get the medicine they need. Many will get their medications free or nearly free. Visit www.pparx.org for assistance.



Want more information?
Register to receive:

Information on central precocious puberty (CPP)

Information on what to expect from
LUPRON DEPOT-PED therapy

Tips for monitoring your child's progress to help you
communicate with your child's doctor

Medication reminders and more

Go to: [www.lupronped.com/lupron-depot-ped/
registration.aspx](http://www.lupronped.com/lupron-depot-ped/registration.aspx)

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

LUPRON DEPOT-PED® 7.5 mg, 11.25 mg, 15 mg for 1-month
(leuprolide acetate for depot suspension) 11.25 mg and 30 mg for 3-month

**Use for LUPRON DEPOT-PED®
(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). 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 she 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 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, and acting aggressive. **Call your child's doctor right away if your child has any new or worsened 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, 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.

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Things to Consider When Treating With LUPRON DEPOT-PED⁷ (leuprolide acetate for depot suspension)

After starting LUPRON DEPOT-PED therapy, your child may experience an increase in signs and symptoms of CPP during the first few weeks of treatment.

Then, he or she will stop making some hormones and you may see pubertal changes stop; they may even be less obvious. You should notify the doctor if your child has menstrual bleeding that continues beyond the second month of treatment, has irritation at the injection site, develops mood swings or behavioral changes, or has any other unusual signs or symptoms.

Missed injections

It's important to keep your scheduled injections so your child can have the right amount of LUPRON DEPOT-PED in his or her body at all times. Missing even one dose or receiving his or her shot a week late could restart the puberty process.

Side effects of treatment

The most common side effects with LUPRON DEPOT-PED are: pain; acne; injection site reactions, including pain, swelling, and abscess; rash, including a painful rash with fever, blisters/sores, and facial swelling; vaginitis/vaginal bleeding/vaginal discharge; increased weight; altered mood; general pain; headache; fluctuating emotions; and hot flushes/sweating.

Monitoring therapy

To determine if your child's current dose is the right level, his or her hormonal response should be monitored 1-2 months after starting therapy (for monthly dosing) or 2-3 months after starting therapy and at month 6 (for 3-month dosing). Your doctor should also be measuring your child's bone age every 6-12 months.

1. Mayo Clinic. Precocious puberty: definition. Available at: <http://www.mayoclinic.org/diseases-conditions/precocious-puberty/basics/definition/con-20029745>. Accessed January 30, 2014. **2.** Saenger P. Novel treatments seem promising for central precocious puberty. Available at: <http://www.healio.com/endocrinology/pediatric-endocrinology/news/print/endocrine-today/%7Bbe447e73-0aab-417e-8ce4-4cb91d8f095d%7D/novel-treatments-seem-promising-for-central-precocious-puberty>. Accessed January 30, 2014. **3.** Muir A. Precocious puberty. *Pediatric Rev.* 2006;27:373-381. **4.** Carel J-C, Léger J. Precocious puberty. *N Engl J Med.* 2008;358:2366-2377. **5.** Mayo Clinic. Precocious puberty: causes. Available at: <http://www.mayoclinic.org/diseases-conditions/precocious-puberty/basics/causes/con-20029745>. Accessed January 30, 2014. **6.** Mayo Clinic Website. Precocious Puberty Complications. Available at: <http://www.mayoclinic.org/diseases-conditions/precocious-puberty/basics/complications/con-20029745>. Accessed June 16, 2015. **7.** Lupron Depot-PED[®] [package insert].

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