

YOU CAN'T CONTROL
Everything they DO
But You can help control CPP

What every caregiver
should know about Central
Precocious Puberty (CPP)



abbvie

WHAT IS PUBERTY?

Puberty normally begins in girls between the ages of 8 and 13 and in boys between the ages of 9 and 14. Rapid growth of muscles and bones, changes in body shape and size, and maturing of reproductive organs (such as ovaries and testes) are some of the physical changes that occur with puberty.



RATES OF DEVELOPMENT

Usually, girls experience puberty at a slightly younger age than boys. Growing children of the same age may develop at different rates, and even large differences may be completely normal. If you have concerns about your child's rate of development, you should speak with your child's doctor.

See the next page for charts outlining normal development in girls and boys.



NORMAL PUBERTY DEVELOPMENT

NORMAL DEVELOPMENT IN GIRLS

Characteristic	Age of first appearance
Breast development	8-13
Pubic hair	8-13
Pubertal growth spurt	8-13
First period	~12
Underarm hair	9-14
Oil- and sweat-producing glands (and onset of acne)	9-14

NORMAL DEVELOPMENT IN BOYS

Characteristic	Age of first appearance
Growth of testicles and scrotum	9-14
Pubic hair	9-14
Pubertal growth spurt	9-14
Growth of penis	9-14
Voice change	10-16
Facial and underarm hair	9-17
Oil- and sweat-producing glands (and onset of acne)	10-16



WHAT IS CPP?

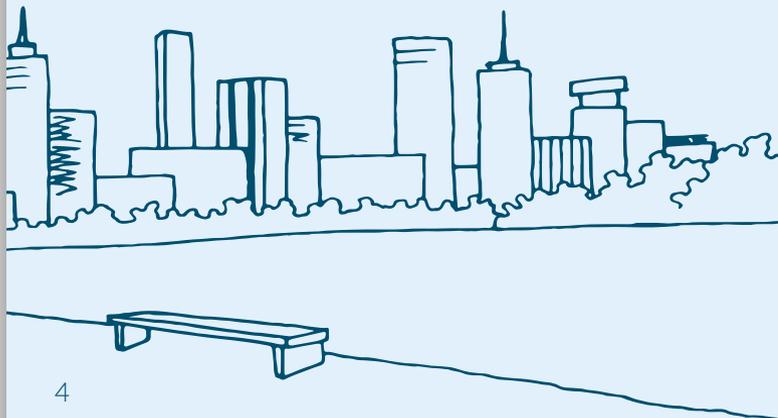
CPP is when puberty starts sooner than it should. For girls, that's before the age of 8, and for boys, before the age of 9. CPP is the most common form of early puberty in children.

- CPP occurs in 1 in 5,000 to 10,000 children
- CPP is 4 to 10 times more common in girls than in boys

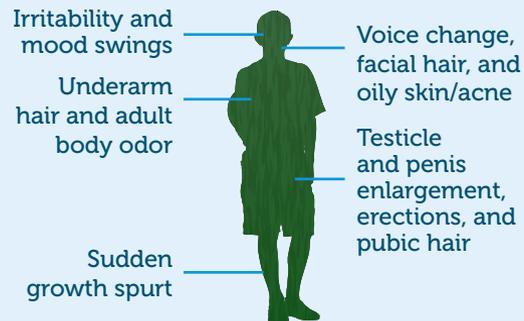
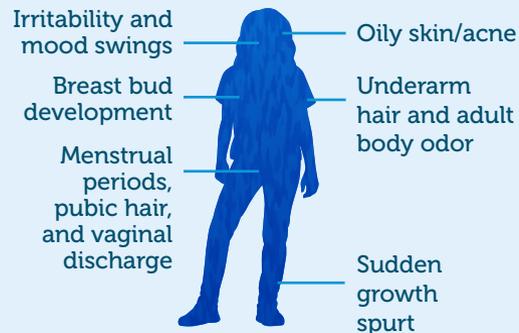
WHAT ARE THE CAUSES OF CPP?

The exact cause of CPP is usually unknown. For the majority of children, there is no underlying medical condition or identifiable reason for CPP, and it is not necessarily passed on from parents to children.

Your child's doctor can perform tests that can help identify a possible cause of CPP.



WHAT ARE THE SIGNS AND SYMPTOMS OF CPP?



If you notice any of these signs and/or symptoms of early puberty in your child, don't wait to talk to their doctor

WHAT HAPPENS IF CPP IS LEFT UNTREATED?

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

— SHORTER ADULT HEIGHT —

- Children with CPP may go through an early growth spurt and be taller than their peers at first because their bones mature quicker than normal
- Once their growth plates close, children stop growing, which may lead to shorter adult height



For illustrative purposes only.

CPP may affect emotional well-being

Children with CPP may face a series of struggles because they look older than they are. Everyday situations and interactions with their peers can become big challenges for them.

IT'S IMPORTANT TO DIAGNOSE AND TREAT CPP EARLY

Diagnosis involves consulting a doctor and conducting several tests, including:

- Thorough physical examination
- X-ray of hand and wrist (helps determine bone age)
- Blood test
- Gonadotropin-releasing hormone (GnRH) stimulation test
- Pelvic or adrenal ultrasound
- MRI or CT scan

There are treatments that can help



The sooner your child starts treatment, the sooner early puberty may slow or stop



LUPRON DEPOT-PED HAS BEEN TRUSTED BY PARENTS AND DOCTORS FOR OVER 30 YEARS

The most common treatment for CPP is called a gonadotropin-releasing hormone agonist (GnRH α). It works by blocking the release of sex hormones in the body. **While on a GnRH α , your child's signs of early puberty should slow or stop**, and your child's growth rate should be more like that of other children their age.

LUPRON DEPOT-PED provided control, pausing early puberty within 4 weeks



96.4% of children taking 1-month LUPRON DEPOT-PED achieved suppression of a reproductive hormone.

Suppression means either pausing early puberty with no changes or reversing the signs of early puberty.

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

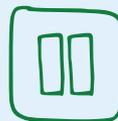
LUPRON DEPOT-PED 7.5 mg, 11.25 mg, and 15 mg for 1-month, 11.25 mg and 30 mg for 3-month, and 45 mg for 6-month administration are prescribed for the treatment of children with central precocious puberty (CPP).

It is not known if LUPRON DEPOT-PED is safe and effective in children less than 1 year old.

Please see Important Safety Information on pages 16-19.

Please see accompanying [Consumer Brief Summary](https://www.rxabbvie.com/pdf/lupronpediatric.pdf) or visit <https://www.rxabbvie.com/pdf/lupronpediatric.pdf> for full Prescribing Information.

WHILE ON LUPRON DEPOT-PED, YOUR CHILD'S EARLY PUBERTY SHOULD BE PAUSED



Your child's growth rate will be normalized, allowing more time for the bones to grow so they can reach their full height potential at an appropriate age. Genital and breast development, as well as menses, should stop or reverse.



The physical signs of early puberty were stopped in most children while on treatment with LUPRON DEPOT-PED. Average growth rates decreased as well.



Go deeper into the data!

<https://www.lupronped.com/about-lupron-depot-ped>



LUPRON DEPOT-PED was studied as a 6-month, 3-month, and 1-month dosing schedule. All LUPRON DEPOT-PED schedules provided control, pausing early puberty in 4 weeks.

Safety Considerations

Your child should not receive LUPRON DEPOT-PED if she/he is allergic to any of the ingredients or if she is or may become pregnant. Increased signs and symptoms of puberty during the first 2 to 4 weeks of treatment may occur. Contact your child's doctor if signs of puberty continue after the second month of treatment.

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

LONG-TERM SAFETY DATA

REPRODUCTIVE DEVELOPMENT AFTER TREATMENT

Patients who were treated with 1-month LUPRON DEPOT-PED were followed into adulthood (age 21).

After treatment, the reproductive development of 20 patients aged 18 to 26 was evaluated:

- **80%** (16 of 20) reported normal menstrual cycles*
- **12 pregnancies** in 7 patients (including multiple pregnancies in 4 patients)
- **4 of 4** women who tried to become pregnant did

*According to the Office on Women's Health, this is similar to women in the United States, with up to 86% having regular bleeding during their childbearing years.



LUPRON DEPOT-PED is the only CPP treatment that has a long-term, 18+ year safety study

Safety Considerations (cont'd)

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 worsening mental symptoms or problems while taking LUPRON DEPOT-PED.

FINAL ADULT HEIGHT

On average, children on LUPRON DEPOT-PED grew taller than the height predicted for them when they were first diagnosed with CPP.



Scan to learn more about the long-term safety data

<https://www.lupronped.com/about-lupron-depot-ped>

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

LUPRON DEPOT-PED OFFERS FLEXIBLE DOSING

Every child has unique needs, including the amount of medicine needed to treat their CPP. **Your child's doctor will ensure they get the right amount of medicine throughout their treatment to suppress the signs of early puberty.**

LUPRON DEPOT-PED offers flexible dosing with individualized 6-month, 3-month, and 1-month options.

DOSING		
6-month dosing	3-month dosing	1-month dosing
45 mg	11.25 mg and 30 mg	7.5 mg, 11.25 mg, and 15 mg
2 injections each year	4 injections each year	12 injections each year



Only LUPRON DEPOT-PED has 6 dosing options

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STARTING YOUR CHILD ON LUPRON DEPOT-PED

After your child's doctor prescribes LUPRON DEPOT-PED:

- LUPRON DEPOT-PED will likely be dispensed by a specialty pharmacy, not your usual local pharmacy
- The specialty pharmacy should call you to arrange delivery and payment
- LUPRON DEPOT-PED will be delivered to your home or your child's doctor's office

LUPRON DEPOT-PED is given as an injection in your child's doctor's office. Make sure you arrange an appointment.

— WHAT HAPPENS NEXT? —

Over time, the doctor may change how much medicine is in your child's injection and/or how often your child gets it. Your child's doctor will decide the right time for them to stop treatment so puberty can resume.



After treatment discontinuation, the reproductive hormones start up again, and your child will continue through puberty like their peers

Safety Considerations (cont'd)

Seizures have been observed in patients taking GnRH agonists, like LUPRON DEPOT-PED, and the risk of seizure may be higher in patients with or without a history of seizures, epilepsy, brain or brain vessel (cerebrovascular) problems or tumors, and in patients taking medications that have been connected to seizures, such as bupropion or selective serotonin reuptake inhibitors (SSRIs). Call your child's doctor right away if your child has a seizure while taking LUPRON DEPOT-PED.

**SUPPORT PLUS:
WE'RE HERE FOR YOU
EVERY STEP OF THE WAY**

Starting a new medication can raise a lot of questions. Support PLUS can help you with:

- Insurance coverage support
- Potential ways to save on your child's prescription
- Live nurse support*

.....
Call our Support PLUS toll-free hotline:
1-855-LUPRON-P (1-855-587-7667),
Monday-Friday, 7AM-7PM CT.
.....

— **LIVE NURSE SUPPORT HOTLINE** —



You can speak with our certified nurses about CPP and treatment with LUPRON DEPOT-PED anytime over the course of your child's therapy—at no cost to you.*

Tell your child's doctor if you are unable to make appointments during the regular hours. Some offices can work with your schedule.

*Certified nurses are provided by AbbVie and do not work under the direction of your healthcare professional (HCP) or give medical advice. They are trained to direct patients to their HCP for treatment-related advice, including further referrals.

SAVE ON YOUR CHILD'S PRESCRIPTION
— **INSTANT SAVINGS CARD** —

Eligible patients may pay as little as \$10 per prescription of LUPRON DEPOT-PED.



Scan to see if you are eligible and request an Instant Savings Card

www.lupronpedsavingscard.com

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myAbbVie Assist

If you are having difficulty paying for your medicine, myAbbVie Assist may be able to help.

Visit AbbVie.com/myAbbVieAssist to learn more.

Safety Considerations (cont'd)

Increased pressure in the fluid around the brain can happen in children taking GnRH agonist medicines, including LUPRON DEPOT-PED. Call your child's doctor right away if your child has any of the following symptoms during treatment with LUPRON DEPOT-PED: headache, eye problems (including blurred vision, double vision, and decreased eyesight), eye pain, ringing in the ears, dizziness, or nausea. Your child's pubertal development could begin again if the injection schedule is not followed.

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

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 child's 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
 - Anger
 - Irritability
 - Acting aggressive
 - Restlessness (impatience)

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.**

- **Increased pressure in the fluid around the brain can happen in children taking gonadotropin-releasing hormone (GnRH) agonist medicines, including LUPRON DEPOT-PED. Call your child's doctor right away if your child has any of the following symptoms during treatment with LUPRON DEPOT-PED:**
 - Headache
 - Eye pain
 - Eye problems, including blurred vision, double vision, and decreased eyesight
 - Ringing in the ears
 - Dizziness
 - Nausea

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 the 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 child's 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

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Important Safety Information for LUPRON DEPOT-PED (cont'd)

Before your child receives LUPRON DEPOT-PED, tell their doctor about all of your child's medical conditions, including if they: (cont'd)

- 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 child's 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 given as a single-dose injection into your child's muscle each month, every 3 months, or every 6 months by a doctor or trained nurse. Your child's 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 reactions such as pain and swelling
- Weight gain
- Headache
- Mood changes

• The most common side effects of LUPRON DEPOT-PED received every 6 months include:

- Injection site reactions such as pain, swelling, and abscess
- Headache
- Mood changes
- Upper stomach pain
- Diarrhea
- Bleeding
- Nausea and vomiting
- Fever
- Itching
- Pain in extremities
- Rash
- Back pain
- Ligament sprain
- Weight gain
- Fracture
- Breast tenderness
- Difficulty sleeping
- Chest pain
- Excessive sweating

These are not all the possible side effects of LUPRON DEPOT-PED.

Call your child's doctor for medical advice about side effects.

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

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 are having difficulty paying for your medicine, AbbVie may be able to help. Visit AbbVie.com/myAbbVieAssist to learn more.

Please see accompanying [Consumer Brief Summary](#) or visit <https://www.rxabbvie.com/pdf/lupronpediatric.pdf> for full Prescribing Information.

IF YOU'RE WORRIED THAT YOUR CHILD MAY HAVE CPP, DON'T WAIT!

Speak with your child's doctor as soon as you can.
They can evaluate your child and confirm an appropriate
diagnosis and treatment plan.



Learn more about
LUPRON DEPOT-PED

<https://www.lupronped.com>



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