

Central Precocious Puberty

*What's happening
to my child*



KEEP CHILDHOOD SIMPLE

fensolvi[®] 
(leuprolide acetate) for injectable
suspension



What is central precocious puberty (CPP)?

“Puberty” is a word for the physical changes that happen over a few years as boys and girls develop sexually into teens and then adults.¹ Changes generally include hair growth in various places on the body; in girls, these changes include breast development and eventually menstruation and in boys, they include growth of the testicles and penis; and for both, a growth spurt which results in significant increases in height.¹

The timing of puberty can be impacted by genetics, nutrition, and socioeconomic status.¹ Puberty usually starts between ages 8 and 13 for girls and 9 and 14 for boys.¹ It can begin as early as age 7 for some African-American girls². If puberty starts earlier, it’s called “precocious puberty,” which means it happens earlier than the normal age range.^{1,3}

The most common type is called central precocious puberty, or CPP.⁴

IMPORTANT SAFETY INFORMATION

FENSOLVI® is a type of medicine known as a gonadotropin releasing hormone (GnRH) agonist. It is used to treat central precocious puberty (CPP) in children 2 years of age and older and is administered as an injection under the skin (subcutaneously) by your child’s healthcare provider.

Please see Important Safety Information on page 14 and enclosed full Prescribing Information.

CPP is rare

It affects about
1 in 5,000 to 10,000 children.¹



Factors associated with higher incidence of CPP⁴

→ Gender

Girls are around 10 times more likely to have CPP than boys⁴

→ Ethnicity/Race

African American girls are more likely to have CPP than girls of other races (this is not seen with boys)⁴

→ International Adoption

It's not clear why, but kids adopted from countries outside the U.S. are 10 to 20 times more likely to develop CPP⁴

→ Obesity

Girls who are significantly overweight are more likely to have CPP than those with lower weights (this is not seen with boys)⁴

IMPORTANT SAFETY INFORMATION

FENSOLVI should not be given to children:

- Who are sensitive to GnRH, GnRH agonists or any of the ingredients in FENSOLVI (your child's doctor can help you know this)
 - Call your child's doctor or get emergency medical help right away if your child has any symptoms of a serious allergic reaction
- Who are pregnant. FENSOLVI can cause birth defects or loss of the baby

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Understanding the science

of Central Precocious Puberty



What causes CPP— and what can happen to kids who have it?

Hormones are chemical substances that regulate body functions. Puberty starts when the brain begins to release “pulses” or “waves” of a hormone called gonadotropin-releasing hormone (GnRH).^{3,5} GnRH causes other hormones to be released, which in turn cause the physical changes that come with puberty (Figure 1).³ In children with CPP, the GnRH waves start at a younger age than normal.^{3,5}

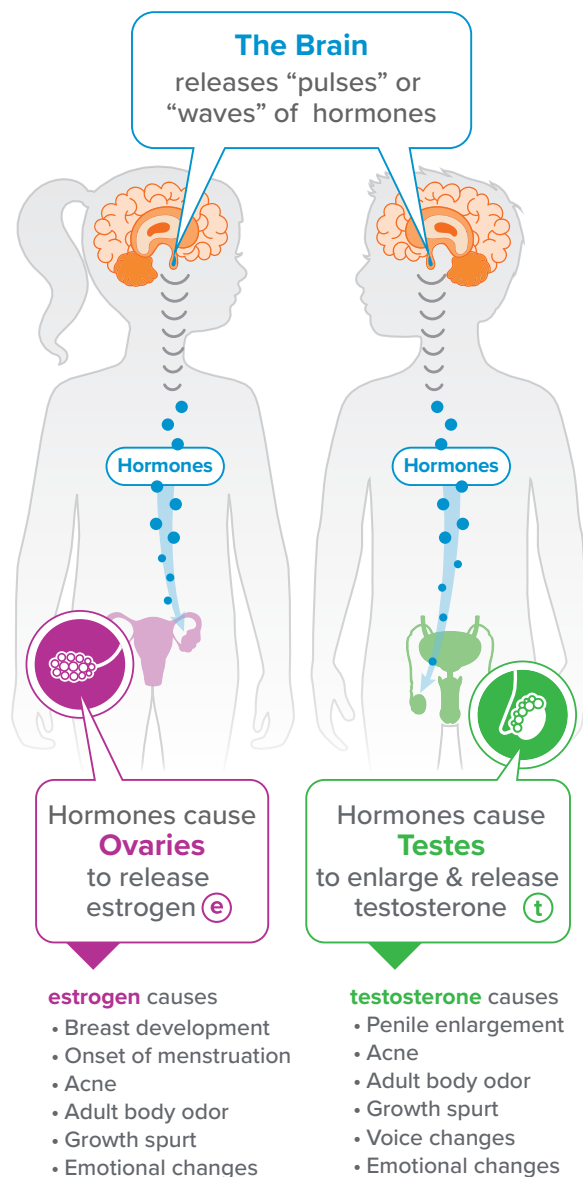
IMPORTANT SAFETY INFORMATION

During the first few weeks of treatment, an increase in signs and symptoms of puberty, including vaginal bleeding in girls, may occur. Some children may have emotional changes with FENSOLVI, including crying, irritability, impatience, anger, or aggression. Call your child’s doctor right away if your child has any new or worsening emotional symptoms while taking FENSOLVI.

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How Puberty Happens

When the body is ready to initiate puberty, the brain begins producing hormones that cause the changes in the body from that of a child into a young woman or man.



Puberty is a tightly regulated process. Sometimes things go wrong with the control of its timing.

Because bone growth is part of puberty, children with CPP may initially be taller than their friends and classmates.^{3,6} But without treatment for CPP, they will stop growing at a younger age and end up much shorter as adults.^{3,6} Untreated CPP may also cause psychological and behavioral issues, as developing physically or sexually ahead of friends and classmates could be emotionally difficult.^{6,7} Children with CPP who are treated can experience normal development into adulthood. Girls should have normal periods, and there should be no impact on ability to become pregnant as adults.^{3,7}

IMPORTANT SAFETY INFORMATION

There have been reports of convulsions (uncontrolled movements due to rapid contraction and relaxation of muscles) in children taking GnRH agonists. Convulsions may occur in children who have not had them before. If your child has a convulsion, call your child's doctor, or get emergency help right away.

Idiopathic Intracranial Hypertension (unexplained elevated pressure in the brain) has been reported in pediatric patients receiving GnRH agonists. Call your child's doctor right away if your child has headaches and/or vision issues.

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IMPORTANT SAFETY INFORMATION

The most common side effects seen in studies with FENSOLVI were injection site pain/redness, colds/sore throat, fever, headache, cough, stomach pain, nausea, constipation, vomiting, wheezing, wet cough and hot flush. Tell your child's doctor about any side effects.

These are not all the possible side effects of FENSOLVI. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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How is CPP diagnosed?

Doctors may diagnose CPP when a girl younger than 8 or a boy younger than 9 is showing signs of puberty. Correct diagnosis of CPP as early as possible is important. CPP is a treatable condition that can be medically managed by your child's doctor.³

Since early signs of puberty can also be caused by things other than CPP, your child's doctor needs to rule out other conditions that would require different treatment.³ There are several steps your child's doctor may take to accurately diagnose CPP and rule out other issues.

How doctors determine if a child has CPP^{7,8}

- Take a medical history for the child (and the family)
- Perform a physical exam
- Take blood for laboratory tests
- Request imaging studies

This information helps rule out other medical problems, so doctors can feel sure about the diagnosis and treatment plan.



As part of getting a **medical history**, questions are asked about when the child's body changes started and how are they progressing, when others in the family started puberty, if there are other symptoms, and details about where the child lives and spends time.⁸



The **physical exam** generally includes an assessment of the child's height and weight over time to determine the rate at which that these change and how each child's values compare to other children of similar age. The development of the child's sex-related organs, nervous system (brain and spinal cord), skin, and abdomen (belly) will also be looked at.⁸



For **laboratory tests**, blood may be drawn to measure different hormones important for sexual development.⁷ A test called the "GnRH stimulation test" may also be done. For this test, an initial blood sample is taken prior to a shot. After the shot, blood is drawn again to measure the amount of several hormones that can increase in response to GnRH.⁷



Finally, different types of **imaging studies** (X-rays, magnetic resonance imaging [MRI], computed tomography [CT] scans, and ultrasounds) may be used to look at the bones, brain, internal sex organs, and hormone-producing glands. These tests provide important information for the doctor.^{7,8}

How do you treat CPP?

The good news about CPP is that it's treatable.^{3,7} Also keep in mind that this is not a lifelong condition and ends when the decision is made to stop treatment and allow puberty to resume. Treatment is important though, as not treating CPP can lead to a shorter adult height, and potential emotional problems as the child develops.⁷

Treatments for CPP block the waves of GnRH hormones that trigger early puberty.³ Treatment stops progression of puberty until the child reaches an age where it is appropriate for puberty to proceed.^{3,7}

Fensolvi® injectable suspension is one of several treatments available for CPP

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Central Precocious Puberty

is treatable

Fensolvi® can help



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What is Fensolvi?⁹

Fensolvi is a medicine called a “GnRH agonist.” It's a small shot of medicine in a gel, given just under the skin. Fensolvi slowly dissolves over 6 months releasing a steady source of drug to the body. This can help stop the waves of GnRH that cause early puberty.



How is Fensolvi given?⁹

Fensolvi is given as a shot just under the skin. This means:

- It's easy to find a place to give the shot, as it can go in most areas that have some fat under the skin
- A short 5/8-inch needle is used
- No need for injections into the muscle
- No surgery needed
- Numbing agents can be used before the shot



How often is Fensolvi given?⁹

Fensolvi is given every 6 months which means:

- Only 2 shots a year
- Shots can be given during your twice-yearly visits to your pediatric endocrinologist's office
- Your child's shot should be given every 6 months as scheduled to make sure the symptoms of puberty do not start again

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Important Safety Information for Fensolvi®



Important Safety Information for Fensolvi

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Please see enclosed full Prescribing Information in pocket of this brochure for additional Important Safety Information.

Summary

- In children with central precocious puberty (CPP), **puberty starts earlier than normal**.^{1,3}
- **CPP is rare**, and much more common in girls than boys.^{1,4}
- **If left untreated**, CPP can lead to reduced adult height, and may cause emotional and behavioral issues.^{3,6,7}
- **Once CPP is diagnosed, it is treatable.** With treatment, children with CPP can maximize their adult height. Studies have shown that treatments of CPP do not interfere with future fertility.^{3,7}
- **Fensolvi is an effective treatment for CPP.** It's given every six months as a shot just under the skin, using a short needle.⁹

— Learn more at fensolvi.com —



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The individuals pictured in this piece are models, and the images are being used for illustrative purposes only.

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