



help keep time on their side

a caregiver's guide to central
precocious puberty

Triptodur[®]
(triptorelin)
for extended release injectable suspension

IMPORTANT SAFETY INFORMATION FOR TRIPTODUR INDICATION

TRIPTODUR is indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP).

IMPORTANT SAFETY INFORMATION

Do not use TRIPTODUR in:

- Those allergic to gonadotropin releasing hormone (GnRH), GnRH agonist medicines, or any ingredients in TRIPTODUR.
- Children under 2 years of age
- Women who are or may become pregnant

Tell your child's healthcare provider if any of the above conditions apply to your child.

Please see additional Important Safety Information continued throughout and accompanying Full [Prescribing Information](#).

Actor
portrayal

PP-TRIP-US-0900

What is central precocious puberty, or CPP?

When a natural process happens too soon

Puberty is a normal part of growing up. For some children, puberty can start too early. When this happens, it may be due to a condition called **central precocious puberty (CPP)**.

CPP is a rare condition that affects

1 in **5,000–10,000** children.³

CPP occurs when a child shows signs of puberty sooner than normal.^{1,2}



Before age

8

in girls



Before age

9

in boys



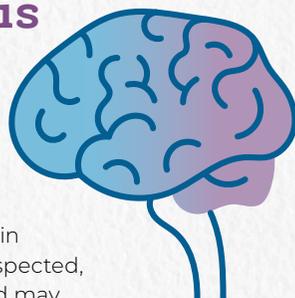
Actor
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If you suspect your child has CPP, it's probably because you've noticed changes in your child's physical development that seem to be happening sooner than they should. This might leave you feeling confused or stressed. It's important to know that there is power in information. Explore this guide to better understand the causes of CPP, the potential symptoms and effects, and a potential treatment option.

CPP causes and diagnosis

Although the exact cause is usually unknown, **CPP results from the early release of a hormone from the brain called gonadotropin-releasing hormone (GnRH).**^{4,5}



A pediatric endocrinologist is a physician who specializes in disorders involving hormones, including CPP. If CPP is suspected, your pediatric endocrinologist will evaluate your child, and may order further testing. Some of those tests could include:⁴



Blood tests to measure hormone levels, including a test called GnRH stimulation test. In children with CPP, GnRH will cause other hormone levels in the body to rise. In children without CPP, these hormone levels will stay the same.



An x-ray of the hand and wrist to measure how fast your child's bones are growing (often called a bone age test or study).



An MRI (magnetic resonance imaging) or CT (computed tomography), which is a scan of the brain that looks to see whether any brain abnormalities are causing puberty to start too soon.

If you notice changes in your child's physical development that seem to be happening too soon, talk to their doctor.

IMPORTANT SAFETY INFORMATION (CONT.)

It is important to stick to the dosing schedule (one injection every 24 weeks) in order for the drug to work. Do not miss or delay a scheduled dose.

Some people taking gonadotropin releasing hormone (GnRH) agonists like TRIPTODUR have had new or worsened mental (psychiatric) problems. Mental (psychiatric) problems may include emotional symptoms such as crying, irritability, restlessness (impatience), anger, or acting aggressive. Call your child's doctor right away if your child has any new or worsening emotional symptoms while taking TRIPTODUR.

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Treating CPP

The good news is that there is **treatment for CPP**. Below are some reasons why you and your child's physician may choose to **move forward with treatment**:



Growth and Height

Your child may have experienced a growth spurt, related to CPP, and may even be tall for his or her age. Treatments for CPP are designed to delay puberty by stopping the signaling of certain hormones that are responsible for jump-starting the puberty process.²

Children with CPP can be taller than their peers, however children that **go untreated may be shorter in height when they become adults**. This is because their growth plates (growth plates are areas of cartilage at the ends of long bones) close too early.⁶ Typically, growth plates close toward the end stages of puberty.



Social and Emotional Impacts

Girls and boys who begin puberty before their peers may be extremely self-conscious about the changes occurring in their bodies. This may affect their self-esteem and may increase their risk of developing depression, eating disorders, or substance abuse.^{4,7-9}

There is no data demonstrating outcome of Triptodur® on stature, social or emotional health.

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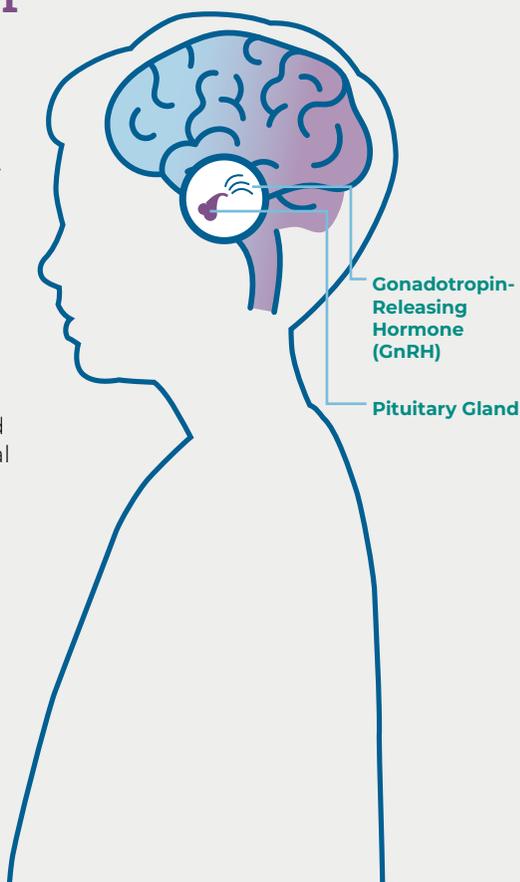
What is Triptodur® (triptorelin)?

Triptodur is an injectable prescription medicine used for the treatment of children 2 years of age or older with **central precocious puberty (CPP)**.¹⁰ It is administered as a single intramuscular (IM) injection once every 24 weeks, making it the **first FDA-approved medicine** for CPP to offer once-every 6-month dosing. Treatment with Triptodur does not require surgery.

How can Triptodur help my child?

To understand how Triptodur works, it helps to know a little about what causes puberty. The process of puberty starts in the brain with the creation of a hormone called gonadotropin-releasing hormone (GnRH). GnRH causes the pituitary gland — a small bean-shaped gland at the base of the brain — to release two more hormones called luteinizing hormone (LH) and follicle-stimulating hormone (FSH). LH and FSH are involved in the growth and development of female and male sexual characteristics.⁵

Treatments for CPP weaken the effects of GnRH signaling on the pituitary gland, reducing the release of hormones that cause puberty. By stopping the signaling of these hormones, the puberty process will be delayed until the end of the treatment. The effect of Triptodur on pituitary and gonadal function is expected to disappear within six to twelve months after treatment is stopped.¹⁰



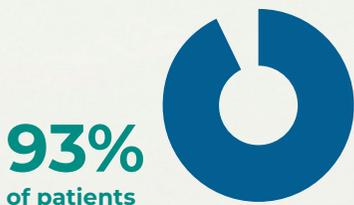
IMPORTANT SAFETY INFORMATION (CONT.)

Some people taking GnRH agonists like TRIPTODUR 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 with 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 TRIPTODUR.

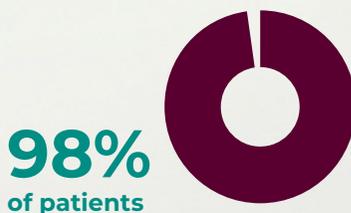
Please see additional Important Safety Information continued throughout and accompanying Full [Prescribing Information](#).

Triptodur® is effective in suppressing luteinizing hormone (LH) to prepubertal levels (≤ 5 IU/L)

In a phase III clinical trial,



receiving Triptodur had their LH suppressed to prepubertal levels at month 6 (primary endpoint)



maintained these levels at 12 months.¹⁰

Triptodur was also found to be well tolerated with no unexpected side effects^{10,11}

Benefits of Triptodur include:



Given only **twice a year** as an intramuscular injection¹⁰



Well tolerated therapy^{10,11}



No surgery required



Long-lasting LH suppression^{10,11}

IMPORTANT SAFETY INFORMATION (CONT.)

Some people taking triptorelin, the active ingredient in TRIPTODUR, have had serious allergic reactions. Call your child's doctor or get emergency medical help right away if your child gets any of the following symptoms of a serious allergic reaction: skin rashes, redness, or swelling, severe itching, hives, trouble breathing or swallowing, fast heartbeat, sweating, throat tightness, hoarseness, swelling of face, mouth, and tongue, dizziness or fainting.

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What to expect during treatment

Triptodur must be administered under the supervision of a physician. It is important to stick to the dosing schedule (1 injection every 24 weeks) in order for the medicine to work. Do not miss or delay a scheduled dose.¹⁰

Your child should have regular visits with his or her pediatrician or pediatric endocrinologist while undergoing treatment for CPP. Your child may need blood tests beginning 1 to 2 months following the start of treatment, during treatment as necessary to confirm efficacy, and with each subsequent dose.

During your child's treatment, a healthcare professional will perform regular exams and blood tests to check for signs of puberty, measure height and weight, and may take wrist X-rays to track bone growth.

The most common side effects of Triptodur include injection site reactions, menstrual (vaginal) bleeding, hot flush, headache, cough, and infections (bronchitis, gastroenteritis, influenza, nasopharyngitis, otitis externa, pharyngitis, sinusitis, and upper respiratory tract infection). Tell your child's healthcare provider if they have any side effect that bothers them or that does not go away.

These are not all the possible side effects of Triptodur. For more information, ask your child's healthcare provider or see the Important Safety Information for more details.

Actor
portrayal



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IMPORTANT SAFETY INFORMATION FOR TRIPTODUR

TRIPTODUR® (triptorelin) for extended-release injectable suspension, for intramuscular use

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In the first few weeks after your child receives their first TRIPTODUR injection or after additional injections, TRIPTODUR can cause a brief 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 signs of puberty continue after 2 months of receiving TRIPTODUR.

Reports of pseudotumor cerebri (idiopathic intracranial hypertension) have been observed in pediatric patients receiving GnRH agonists, including triptorelin. Patients and caregivers should contact their healthcare provider if the patient develops any of following symptoms of pseudotumor cerebri, including headache, and vision issues such as blurred vision, double vision, loss of vision, pain behind the eye or pain with eye movement, ringing in the ears, dizziness, and nausea.

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To report SUSPECTED ADVERSE REACTIONS, contact Azurity Pharmaceuticals, Inc. at 1-800-461-7449, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

The Important Safety Information does not include all the information needed to use TRIPTODUR safely and effectively. For additional safety information, please consult the full Prescribing Information for TRIPTODUR.

IMPORTANT SAFETY INFORMATION (CONT.)

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Guiding your child through treatment

Keeping track of your child's growth

During treatment, it's helpful to tell your doctor about any changes you see in your child's body such as: height, growth of underarm and pubic hair, breast development, voice change, and oily skin and acne.

Aside from the classic pencil markings on the doorway, there are other fun, interactive ways to make tracking your child's body changes less clinical, and more fun!



Art Project

Create a giant ruler or use blank measuring tape with your child that you can use to track body changes, but there's also plenty of room to create fun designs and drawings together!

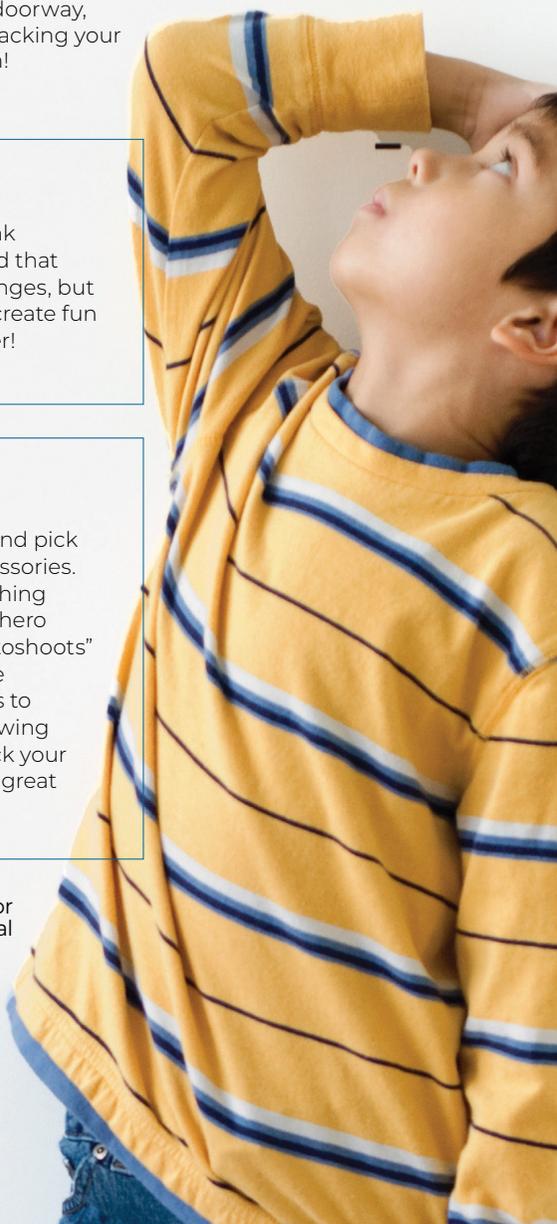


Photoshoot

Let your child go to the store and pick out some of their favorite accessories. These accessories can be anything such as tiaras, scarves, a superhero costume, etc. Do regular "photoshoots" with your child using the same accessories and clothing items to track how fast they are outgrowing the items. You'll be able to track your child's growth and have some great photos for your memories!

Actor
portrayal

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Talking to your child about CPP: a helpful guide

Going through puberty too early can be a confusing and unsettling time for a child and his or her family. There are changes taking place in your child's body that he or she may not fully understand.⁹

As a parent, you play a key role in helping your child understand central precocious puberty (CPP).¹² This guide includes some helpful tips to keep in mind as you discuss CPP with your child.

for children ages 3-6:

Tip #1:

Communication.
**Reinforce that your child's
body is normal.**

At such a young age, your child might not be fully aware of the changes happening in his or her body, and may even seem unaffected by it. However, children may ask questions about why they are going to the doctor, or why they have to get tests or treatment. If your child is tall or perhaps more developed for their age, he or she may also have other children or adults comment or ask questions about their growth.



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portrayal

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How you talk about CPP can go a long way toward shaping your child's understanding of it, so it is a good idea to think about how you will discuss CPP with your child. It may be helpful to start with something like: "Everyone's body goes through these changes. Your body just started a little early."

It may also be helpful to use objects to open lines of communication between you and your child about the changes in his or her body. Comparing the size of objects such as toys gives children a chance to play with measurement and helps them learn how to compare and use words such as "taller," "shorter," etc.¹³

For example, directly compare the heights of two stuffed toys and describe one toy as taller/shorter. This not only helps children understand measurement, but can help guide the conversation between you and your child about which parts of his or her body is growing or changing.

Tip #2: **Prepare yourself so you can best help your child.**

A CPP diagnosis can raise a lot of questions: What's happening to my child's body? Who do I talk to if I need help? Do I tell my friends and family?

Children often mimic their parent's behavior—your child is more likely to be anxious if you exhibit signs of stress.¹⁴ Understanding CPP, and how you plan to talk with your child, family members, and even your doctors, can empower you to be a reliable support system for your child.

A simple explanation of CPP that can be used with friends and family is "My child has started puberty sooner than normal."

By talking to your child's doctor about CPP and what to expect, you can help ease your own uncertainties and anxieties.

Tip #3: **Treat them according to their age.**

Although your child's body is developing early, he or she is still a young child. Sometimes adults or other children may treat your child as if they are older because of their appearance.⁹ If you are worried about family members, teachers, or other adults in your child's life treating him or her as if they are older, it may be helpful to explain the condition to them. Talk to your healthcare provider for suggestions on explaining CPP or share this helpful guide.

IMPORTANT SAFETY INFORMATION (CONT.)

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for children ages 7 and up:

Tip #1:

Stay positive. Reinforce that your child is going through a natural process that usually happens at a later age.⁶

Right now, your child might not understand the changes happening in his or her body and may have negative feelings about developing early. How you talk about CPP can go a long way toward shaping your child's understanding of it. When discussing CPP, it is helpful to be open and honest about the changes happening to your child's body.¹⁵ You can start out by saying something like: "Everybody goes through puberty. You just started a little early."

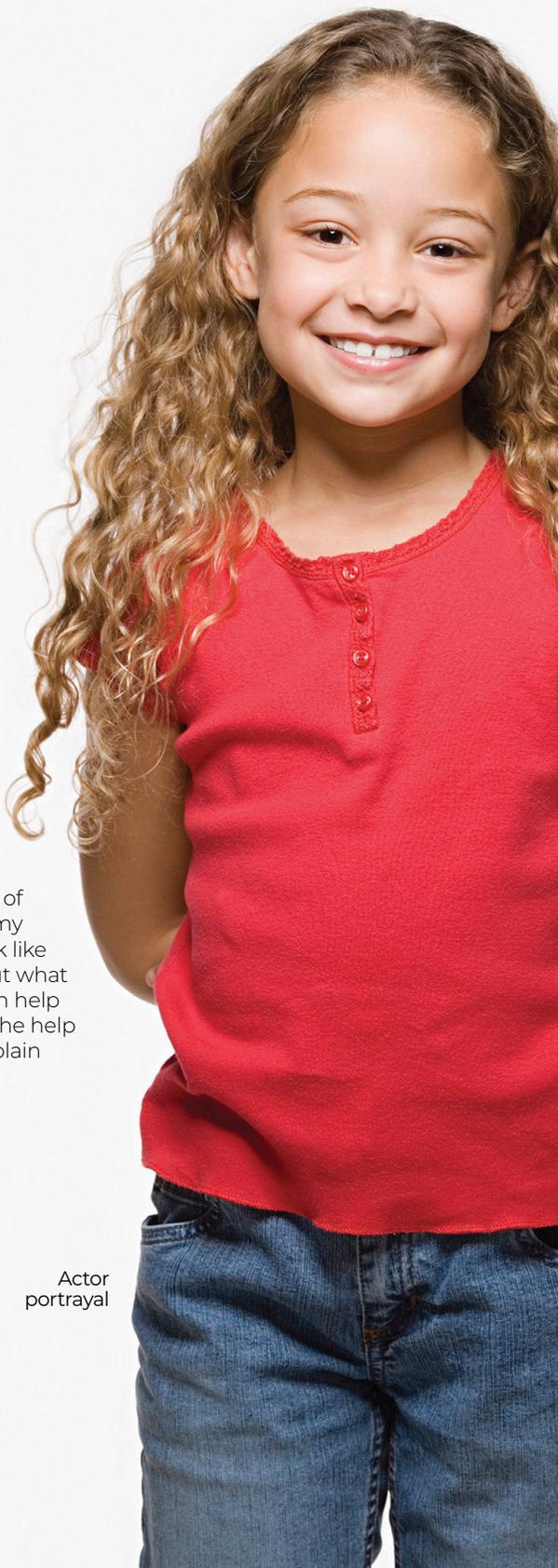
Tip #2:

Prepare your child for what to expect.

Being diagnosed with CPP can raise a lot of questions such as: What's happening to my body? Why am I moody? Why don't I look like my friends?⁹ By talking to your child about what CPP is and what to expect from it, you can help ease his or her fears and anxieties. Enlist the help of your child's health care providers to explain what is happening. Be sure to stay involved.

Actor
portrayal

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Tip #3:
Be there.

Although your child's body is developing early, he or she is still a child and needs your support and guidance. Reassure your child that you're there when he or she has questions, concerns, or just wants to talk. It may be helpful to tell your child: "I'm here to help you" or "You can ask me anything."⁹

Tip #4:
Help your child feel comfortable responding to questions.

Because it's natural for other people—especially kids—to be curious, it helps to arm your child with some simple responses to questions he or she may get from other kids. A confident, straightforward response to other people's curiosity can help.¹⁵

For example, if one of your daughter's classmates asks her why she has breasts, you may want to suggest that she smile and say, "Because I'm a girl." Or your child might choose a more direct approach and simply answer: "I have a medical condition" and leave it at that. The important thing is for your child not to feel ashamed or embarrassed about CPP.⁹

Children look for guidance on how to think about and respond to CPP. Your love and support means everything and can go a long way to boosting your child's self-acceptance.⁹

IMPORTANT SAFETY INFORMATION (CONT.)

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Caregiver Resources

Triptodur® is with you every step of the way through treatment.

Parents and caregivers receive comprehensive support services with the Triptodur Care Program.

Insurance, co-pays, and benefits can be difficult to navigate. **The Triptodur Care Program** offers you support before, during, and after treatment.



Co-pay Savings Program



Dedicated and Trained Staff



Benefits and Insurance Support

To learn more about the Triptodur Care Program and co-pay support, call us toll free at 833-401-CARE or visit www.triptodur.com.

Below are some **organizations and resources for parents and caregivers** caring for a child with central precocious puberty (CPP).



HUMAN GROWTH FOUNDATION

The Human Growth Foundation leads the way in providing research, education, support, and advocacy in areas of growth or growth-hormone disorders.

<http://hgfound.org/>



MAGIC FOUNDATION

The MAGIC Foundation is the world's largest organization for children and adults with growth-related disorders.

<https://www.magicfoundation.org/>

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growing up
happens fast,
help keep time
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