

Starting With Fensolvi®:
What to expect



KEEP CHILDHOOD SIMPLE

fensolvi® 
(leuprolide acetate) for injectable
suspension

Who is this brochure for?

This brochure is for parents or guardians of children who've been diagnosed with central precocious puberty, or CPP. If you need more information, or have any worries, your child's doctor or nurse will be happy to help.



What is central precocious puberty (CPP)?

Puberty starts when the brain releases “pulses” or “waves” of a hormone called gonadotropin-releasing hormone (GnRH). In children with CPP, this happens at a younger age than expected.^{1,2} Doctors diagnose CPP when signs of puberty are seen in girls younger than 8 or boys younger than 9.^{1,2} It's important for your child's doctor to rule out other conditions that may be causing early signs of puberty, so your child can get the right treatment.¹

CPP can be treated by giving a medicine that prevents the brain from releasing the frequent waves of GnRH and stops the progression of puberty.¹ When it's time for normal puberty to start, your child's doctor can stop treatment, allowing the brain to begin releasing waves of GnRH again.³

Central precocious puberty (CPP) is treatable. Fensolvi® (leuprolide acetate) for injectable suspension can help.

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 10 and [click](#) for full Prescribing Information.

What is Fensolvi?

Fensolvi® is a treatment that gives your child a steady source of medicine to help block the progression of puberty. The shot is given in your child's doctor's office.⁴ Your child does not have to do anything special before or immediately after the visit.⁴ The doctor will monitor your child at regular intervals; 1-2 months after the first Fensolvi injection to make sure the treatment is working as expected, and then every 3-6 months to check your child's height.



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What is Fensolvi?⁴

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



How is Fensolvi given?⁴

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
- Local anesthesia can be used to numb the area

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

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How often is Fensolvi given?⁴

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 to reoccur

IMPORTANT SAFETY INFORMATION

FENSOLVI should not be given to children:

- Who are pregnant. FENSOLVI can cause birth defects or loss of the baby

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.

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.

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*Fensolvi is needed
just twice a year!*



What should I expect as my child starts treatment?

It's important to know that your child's puberty symptoms may get worse for a short time at the start of treatment. This is because of the way the medicine works and it can take up to 3 weeks for the treatment to stop the waves of GnRH that are causing puberty. After that, symptoms should start to get better—and your child can go back to simply being a child!⁴

If you have questions about CPP or Fensolvi®, be sure to ask your child's doctor or nurse. Please also read the safety information at the end of this brochure.

IMPORTANT SAFETY INFORMATION

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.

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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What kind of support is available?

Fensolvi® has a great support program that provides information that will make the CPP treatment process easier for you. Whether you want to learn more about Fensolvi, are wondering about a potential side effect, or just need a reminder when it's time to go back to the doctor for the next treatment, we've got you covered.



Copay assistance

We know the financial aspect of CPP treatment can be challenging—and we have a comprehensive, best-in-class patient access program to help your child get the treatment that he or she needs.

With **Fensolvi TotalSolutions**, you can pay as little as \$5 for your Fensolvi prescription. Your doctor or nurse can quickly and easily assist you in enrolling in the program.

A dedicated line for healthcare providers helping patients get access to Fensolvi



1-866-FENSOLVI
(1-866-336-7658)

Monday through Friday
8:00am to 8:00pm
(Eastern Time)



The Fensolvi® Co-pay Assistance Program ("Program") is valid **ONLY** for patients who are prescribed Fensolvi® and are reimbursed exclusively by commercial insurance. This Program is valid only in the United States; but, void where prohibited by law or by the patient's health insurance provider. This Program is non-transferable, limited to one per person, and cannot be combined with any other coupon, free trial, discount, prescription savings card, or other offer. Restrictions or limits may apply.

Medicare, Medicaid, Tricare and other federal health care program beneficiaries may not participate in this Program. This Program also is neither available for cash paying patients or where your commercial plan reimburses you for the entire cost of your prescription drug. Patients cannot seek reimbursement from health insurance or any third party for any part of the assistance received through this Program. The patient or his/her guardian is responsible for reporting the receipt of all benefits or reimbursement received under the Program to any insurer, health plan, or other third party, as may be required. This Program is not insurance and is not intended as a substitute for insurance.

With the Program, you pay as little as \$5 of your co-pay or co-insurance for Fensolvi®, per prescription. The remainder of your co-pay or co-insurance is covered, up to a \$10,000 yearly limit. The total assistance under this Program in any calendar year may not exceed \$10,000.

Tolmar Pharmaceuticals, Inc. ("Tolmar") reserves the right to terminate, rescind, revoke, or modify this Program at any time without notice. This Program expires at the end of the current calendar year, at which time you must re-enroll. For complete information about the terms and conditions of this Program, including the limitations on use and the amount of assistance, go to: www.fensolvi.com or call 1-866-FENSOLVI (1-866-336-7658).

Program managed by ConnectiveRx on behalf of Tolmar.

Important Safety Information for Fensolvi®



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Please [click](#) for full Prescribing Information and additional Important Safety Information.

Summary

- **Puberty starts** when the brain releases “pulses” or “waves” of a hormone called gonadotropin-releasing hormone (GnRH).^{1,2} In children with central precocious puberty (CPP), this happens at a younger age than expected.^{1,2}
- **Fensolvi® is a treatment** that gives your child a steady source of medicine to help block the progression of puberty.¹
- **Fensolvi is an effective treatment for CPP.** It's given every 6 months as a shot just under the skin, using a short needle.⁴
- **Fensolvi has a great support program** that provides information that will make the CPP treatment process easier for you.
- With **Fensolvi TotalSolutions™**, you can pay as little as \$5 for Fensolvi. Your doctor or nurse can quickly and easily assist you in enrolling.

— Learn more at fensolvi.com —

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REFERENCES

1. Precocious puberty. National Organization for Rare Disorders (NORD). <https://rarediseases.org/rare-diseases/precocious-puberty/>. 2016. Accessed January 6, 2019.
2. Partsch C-J, Sippell WG. Pathogenesis and epidemiology of precocious puberty. Effects of exogenous oestrogens. Human Reproduction Update. 2001;7(3): 292–302.
3. Precocious puberty: Diagnosis and treatment. Mayo Clinic. <https://www.mayoclinic.org/diseases-conditions/precocious-puberty/diagnosis-treatment/drc-20351817>. 2019. Accessed October 3, 2019.
4. Fensolvi® (leuprolide acetate) for injectable suspension 45 mg Prescribing Information. Dublin 2, Ireland: Tolmar International, Ltd.; 2020.

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

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