

TREAT CPP

# Just Below the Surface

The treatment of central precocious  
puberty (CPP) has evolved to  
**subcutaneous (SC) injections**

Designed specifically  
for pediatric patients



The shortest needle  
at only 5/8 inch



The smallest injection  
volume at 0.375 mL



The only 6-month subcutaneous  
injection of leuprolide acetate



LH suppression for the duration  
of the dosing period




Only Fensolvi<sup>®</sup> delivers the **30-year reliability of leuprolide acetate with innovations**  
that can help make a real difference in the patient treatment experience.

**Important Safety Information:** FENSOLVI<sup>®</sup> (leuprolide acetate) for injectable suspension is a gonadotropin releasing hormone (GnRH) agonist used to treat patients 2 years of age and older with central precocious puberty (CPP). CPP may be diagnosed when signs of sexual maturity begin to develop in girls under the age of 8 or in boys under the age of 9.

FENSOLVI is contraindicated in individuals with hypersensitivity to any drug that is in the same class as FENSOLVI, in individuals who are allergic to any of the ingredients in FENSOLVI, or in individuals who are pregnant. FENSOLVI may cause fetal harm when administered to a pregnant patient. **See additional important Safety Information inside and full Prescribing Information in Pocket.**

PRODUCT INNOVATION


Fensolvi® (leuprolide acetate) for injectable suspension  
The **first and only subcutaneous** injection of **leuprolide acetate** for the treatment of CPP administered **every 6 months**<sup>1</sup>





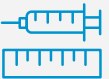

Easy to mix  
**Pre-connected  
Syringe System**

Small injection volume<sup>1</sup>  
**0.375 mL**

Short needle<sup>1</sup>  
**5/8 in.  
18G Needle**



Fensolvi Innovations: Designed With A Child In Mind

 <b>Leuprolide Acetate</b>	<b>FEATURES</b>	 <b>Subcutaneous Injection</b>	 <b>Shortest Needle</b>	 <b>Smallest Injection Volume</b>
<b>The most commonly prescribed CPP treatment</b>		<ul style="list-style-type: none"><li>Lack of “the-day-after” muscle pain typically associated with IM injection<sup>2</sup></li><li>Reduced risk of hitting bone or nerve<sup>2</sup></li><li>No surgery or product removal required</li></ul>	<ul style="list-style-type: none"><li>5/8 inch needle length</li><li>Shorter length may be less likely to cause fear of needle<sup>3</sup></li></ul>	<ul style="list-style-type: none"><li>Low injection volume of 0.375 mL<sup>1</sup></li><li>Smallest injection volume among the GnRHa injectables for CPP<sup>1</sup></li></ul>

**Important Safety Information (continued):** During the first few weeks of treatment, increases in gonadotropins and sex steroids above baseline may result in an increase in signs and symptoms of puberty including vaginal bleeding in girls.

PRODUCT ACCESS

Fensolvi can be accessed multiple ways:  
**Talk to your Tolmar representative about your preferred way to procure Fensolvi®**

**1 Fensolvi TotalSolutions® Hub**

Use your current eRx platform  
Send a prescription directly to Fensolvi TotalSolutions® via the **Careform Pharmacy** (NPI 1043762750)\*

100 Emerson Ln., Ste 1515  
Bridgeville, PA 15017  
**Phone:** 412-250-4407  
**Fax:** 412-774-9652  
**NCPDP Number:** 6007909

Utilize the on-line portal  
FensolviTotalSolutions.com  
1-866-FENSOLVI  
(1-866-336-7658)

Fax patient enrollment form  
Fax: 1-412-520-3442

\* Patient benefits investigation and verification of insurance coverage are provided as a service by the ConnectiveRx non-commercial, non-dispensing pharmacy (Careform Pharmacy).

**2 Specialty distributor**

- Order Fensolvi through one of our Specialty Distributor partners
- Bill Fensolvi as you would other office-based injections

**3 Integrated specialty pharmacy within your institution**

Prescribe Fensolvi to your system-based SP as you do with other prescriptions

**Additional assistance from a Patient Access and Reimbursement Manager (PARM)**

To contact a PARM, please call Fensolvi® TotalSolutions® at **1-866-FENSOLVI** (1-866-336-7658) or email **fensolvi@tolmar.com**

Learn more at **Fensolvi.com/hcp**  
**See full Prescribing Information in Pocket.**






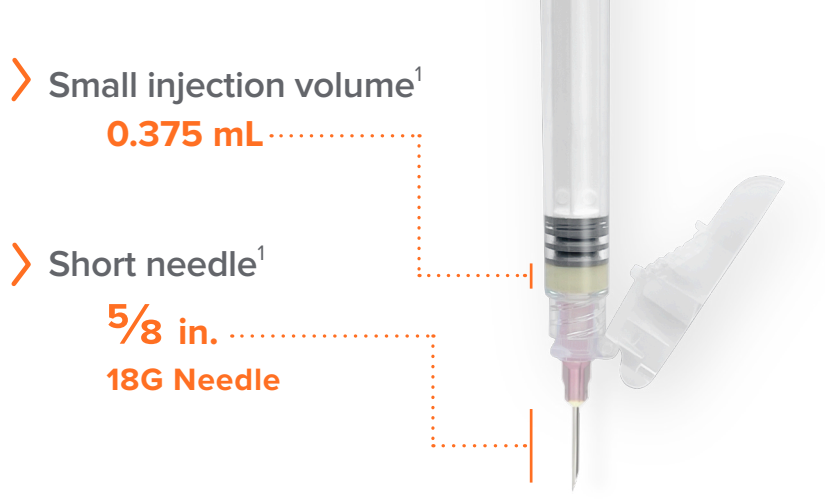
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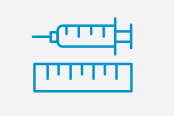

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Fensolvi Innovations: Designed With A Child In Mind

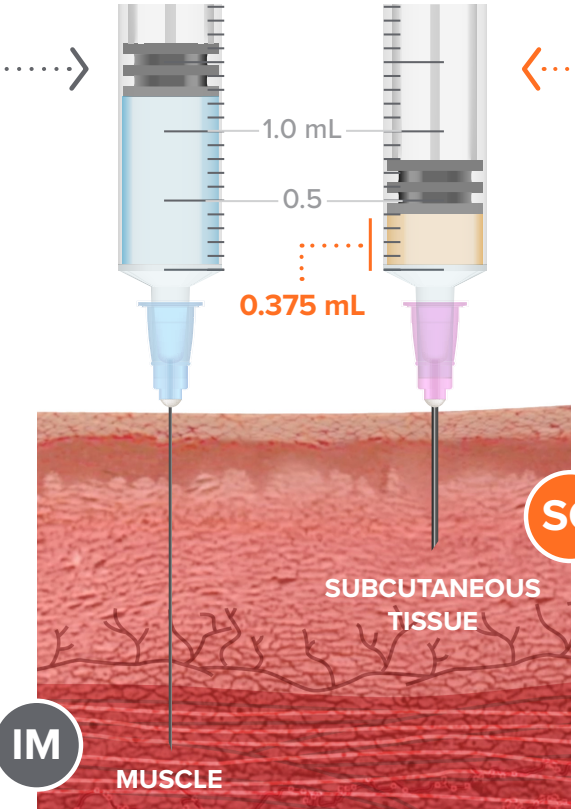
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Intramuscular (IM) vs. Subcutaneous (SC) Considerations for children’s injection experience

**Intramuscular Injection (IM)<sup>2</sup>**

- Higher risk of bone or nerve injury due to:
  - Longer needle
- Limited injection sites
- No surgery required




IM: 1.0 mL, 0.5 mL, 0.375 mL  
SC: 0.375 mL

MUSCLE  
SUBCUTANEOUS TISSUE

**Subcutaneous Injection (SC)<sup>2</sup>**


- Most recent CPP treatment innovation
- Lack of muscle pain typically associated with IM injections<sup>2</sup>
- Little muscle mass (common among children) is not a concern<sup>2</sup>
- Lower risk of bone or nerve damage<sup>2</sup>
- Flexibility of injection sites<sup>2</sup>
- No surgery required

A recent review by an international group of experts highlighted trends in the care of children with CPP including giving long-acting injections subcutaneously rather than intramuscularly.<sup>4</sup>



For more information, watch the Fensolvi Product Video

Scan this QR code with your smartphone’s camera.



fensolvi®  
(leuprolide acetate) for injectable suspension

**Important Safety Information (continued):** Psychiatric events have been reported in patients taking GnRH agonists. Events include emotional lability, such as crying, irritability, impatience, anger, and aggression. Patients should be monitored for development or worsening of psychiatric symptoms.

Convulsions have been observed in patients treated with GnRH agonists with or without a history of seizures, epilepsy, cerebrovascular disorders, central nervous system anomalies or tumors, and in patients on concomitant medications that have been associated with convulsions such as bupropion and SSRIs.

Pseudotumor Cerebri (Idiopathic Intracranial Hypertension) has been reported in pediatric patients treated with GnRH agonists. Patients should be monitored for headache, papilledema and blurred vision.

The most common adverse events seen with FENSOLVI were: injection site pain, nasopharyngitis, pyrexia, headache, cough, abdominal pain, injection site erythema, nausea, constipation, vomiting, upper respiratory tract infection, bronchospasm, productive cough and hot flush. **See full Prescribing Information in Pocket.**

**EFFICACY & SAFETY**

**Fensolvi® was proven to be effective and well-tolerated in the pivotal trial**

97% of children had **regression or stabilization of Tanner staging** during 48 weeks of treatment<sup>5</sup>

**Mean height velocity decreased from Week 4 to Week 48**, from 8.9 cm/year to 6.4cm/year<sup>1</sup>

**Mean difference between BA and CA decreased**, from 3 years to 2.7 years<sup>1</sup>

BA = Bone Age; CA = Chronological Age

**CLINICAL RESULTS**

**No children withdrew** from the study due to adverse reactions

**BIOCHEMICAL RESULTS**

- ≥97%** of girls achieved **estradiol suppression** to pre-pubertal level throughout 48 weeks of treatment<sup>1</sup>
- 94%** of children achieved **peak stim LH of <5 IU/L** at week 24<sup>1</sup>
- 87%** of children achieved **primary endpoint of peak stim LH of <4 IU/L** at week 24<sup>1</sup>

Fensolvi® has a well-established safety and tolerability profile<sup>1</sup>

Adverse reactions occurring in ≥5% of patients treated with Fensolvi in an open-label, single-arm trial<sup>1</sup>

Other adverse reactions

- Psychiatric emotional disorder (2%) and irritability (2%)
- No adverse reactions led to withdrawal from the study or discontinuation of Fensolvi<sup>1</sup>
  - Throughout the 12 months of the clinical trial, no serious adverse events or significant adverse events of clinical relevance occurred<sup>1</sup>

Adverse reactions	% of patients
Injection site pain—All injections site pain was mild/grade 1 (82% injections delivered with numbing agent)	31%
Nasopharyngitis	22%
Pyrexia	17%
Headache	16%
Cough	13%
Abdominal pain	9%
Injection-site erythema	9%
Nausea	8%
Constipation	6%
Vomiting	6%
Upper respiratory tract infection	6%
Bronchospasm	6%
Productive cough	6%
Hot flash	5%

(N = 64)

Learn more at **Fensolvi.com/hcp**

**See full Prescribing Information in Pocket.**

## STORAGE

Fensolvi<sup>®</sup> is a refrigerated product. However, once received, it can be stored at room temperature (59-86°F) for up to 8 weeks



## PACKAGING DIMENSIONS

10.875" w x 3.2" h x 1.4" d

## eRX

Send a prescription directly to Fensolvi TotalSolutions<sup>®</sup> via the **Careform Pharmacy** (NPI 1043762750)  
100 Emerson Ln., Ste 1515, Bridgeville, PA 15017  
**Phone:** 1-412-250-4407  
**Fax:** 1-412-774-9652  
**NCPDP Number:** 6007909

## ON-LINE PORTAL

FensolviTotalSolutions.com  
**Phone:** 1-866-FENSOLVI (1-866-336-7658)

## PATIENT ENROLLMENT FAX

1-412-520-3442

## RELEVANT CODES

NDC 62935-163-60 (shown on package)  
NDC 62935-0163-60 (for billing purposes)

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1. Fensolvi<sup>®</sup> (leuprolide acetate) for injectable suspension 45 mg Prescribing Information. Dublin 2, Ireland: Tolmar International, Ltd.; 04/2022.  
2. Prettyman J, Engel L, Boldt-Houle D, et al. Personalizing treatment in the delivery of care by nurses to patients with prostate cancer. Urologic Nursing. 2019;39(2):83-99. 3. Nagai Y, Ohshige T, Arai K, Kobayashi H, Sada Y, Ohmori S, et al. Comparison between shorter straight and thinner microtapered insulin injection needles. Diabetes Technol Ther. (2013) 15:550-5. 4. Popovic J, Geffner M, Rogol A, et al. Gonadotropin-releasing hormone analog therapies for children with central precocious puberty in the United States. Front Pediatr. 2022;10:1-12. 5. Klein K, Freire A, Gryngarten M, et al. Phase 3 trial of a small-volume subcutaneous 6-month duration leuprolide acetate treatment for central precocious puberty. J Clin Endo Metab. 2020;105(10):1-12.

Fensolvi can be filled by our network of specialty pharmacies

## Specialty Pharmacy Network

### Specialty Pharmacy Partners

CVS Specialty Pharmacy  
Kroger Specialty Pharmacy  
Maxor Specialty Pharmacy

### Fensolvi HUB

Fensolvi TotalSolutions<sup>®</sup>  
1-866-fensolvi (336-7658)

## Specialty Distribution Partners

Specialty Distributors	Fensolvi Item Number
Cardinal Health Specialty Distribution	5645098
CuraScript SD	409332
McKesson Specialty Distribution	5010287

## Hospital Distribution Partners

Distributors	Fensolvi Item Number
Amerisource Bergen Drug Company	10235782
Cardinal Health	5645387
Henry Schein	325-0373
McKesson	1549898
Morris & Dickson	903518