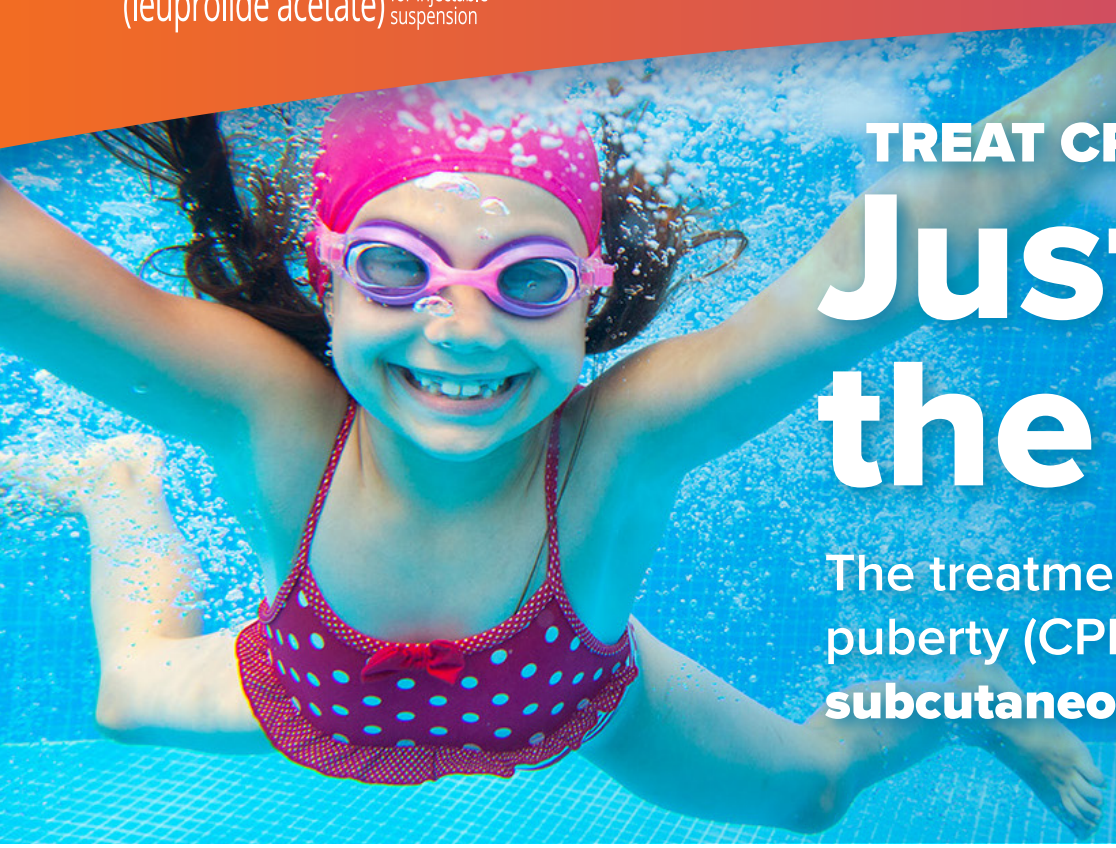
fensolvi®
(leuprolide acetate) for injectable suspension

Learn more at
Fensolvi.com/hcp



TREAT CPP

Just Below the Surface

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

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

Designed specifically **for pediatric patients**

- The shortest needle at only 5/8 inch[1,2,3]
- The only 6-month subcutaneous injection of leuprolide acetate[1]
- The smallest injection volume at 0.375 mL[1,2,3]
- LH suppression for the duration of the dosing period

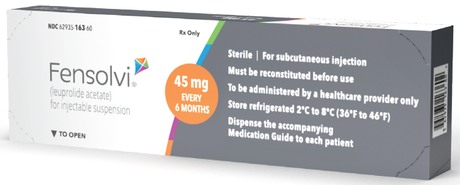
Important Safety Information: FENSOLVI® (leuprolide acetate) for injectable suspension is a gonadotropin releasing hormone (GnRH) agonist used to treat patients 2 years of age and older with central precocious puberty (CPP). CPP may be diagnosed when signs of sexual maturity begin to develop in girls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

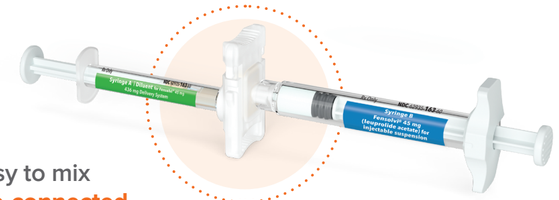
FENSOLVI is contraindicated in individuals with hypersensitivity to any drug that is in the same class as FENSOLVI, in individuals who are allergic to any of the ingredients in FENSOLVI, or in individuals who are pregnant. FENSOLVI may cause fetal harm when administered to a pregnant patient. **See additional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

PRODUCT INNOVATION

Fensolvi® (leuprolide acetate) for injectable suspension

The **first and only 6 month, subcutaneous** injection of **leuprolide acetate** for the treatment of CPP[1]





Easy to mix
Pre-connected Syringe System

Designed with a child in mind

Smallest Injection Volume – 0.375 mL

Smallest injection volume among the GnRHa injectables for CPP[1,2,3]

Shortest Needle[1,2,3] – 5/8 inch, 18 guage

Shorter length may be less likely to cause fear of needle[4]

Fully-prepped, injection-ready Fensolvi

LH suppression

for the duration of the dosing period via a novel insitu polymeric gel delivery system[5]

Leuprolide Acetate

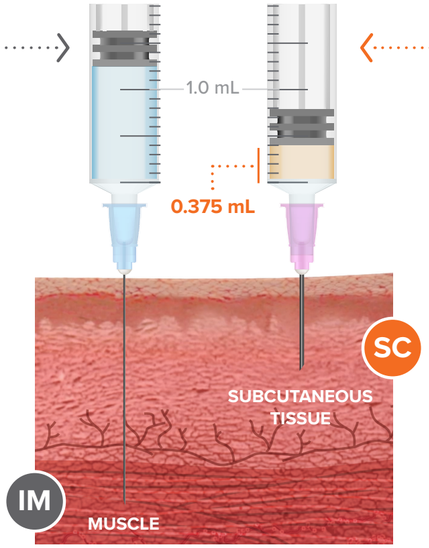
The most commonly prescribed CPP treatment[6]

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.

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

Intramuscular Injection (IM)[7,8,9]

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



Subcutaneous Injection (SC)[7,8,9]

- Most recent CPP treatment innovation[1]
- Lack of muscle pain typically associated with IM injections
- Little muscle mass (common among children) is not a concern
- Lower risk of bone or nerve damage
- Flexibility of injection sites[1]
- 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.[10]

For more information, watch the Fensolvi Product Video

Scan this QR code with your smartphone's camera.

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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

fensolvi® (leuprolide acetate) for injectable suspension

CLINICAL RESULTS

97% of children had **regression or stabilization of Tanner staging** during 48 weeks of treatment[11]

97%

Mean height velocity decreased from Week 4 to Week 48, from 8.9 cm/year to 6.4cm/year[1]

Near Pre-Pubertal

Mean difference between BA and CA decreased, from 3 years to 2.7 years[1]

BA-CA

BA = Bone Age; CA = Chronological Age

No children withdrew from the study due to adverse reactions

BIOCHEMICAL RESULTS

≥97%

≥97% of girls achieved estradiol suppression to pre-pubertal level throughout 48 weeks of treatment[1]

87%

87% of children achieved primary endpoint of peak stim LH of <4 IU/L at week 24[1]

94%

94% of children achieved peak stim LH of <5 IU/L at week 24[12]

Fensolvi® has a well-established safety and tolerability profile[1]

Adverse reactions occurring in ≥5% of patients treated with Fensolvi in an open-label, single-arm trial[1]

Other adverse reactions

Psychiatric emotional disorder (2%) and irritability (2%)

- No adverse reactions led to withdrawal from the study or discontinuation of Fensolvi[1]
- Throughout the 12 months of the clinical trial, no serious adverse events or significant adverse events of clinical relevance occurred[1]

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)

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References: 1. Fensolvi® (leuprolide acetate) for injectable suspension 45 mg Prescribing Information. Dublin 2, Ireland: Tolmar International, Ltd.; 2022 **2.** LUPRON DEPOT-PED [package insert]. North Chicago, IL: AbbVie Inc. https://www.rxabbvie.com/pdf/lupronpediatric.pdf **3.** Triptodur [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC. https://triptodur.com/assets/pdf/Triptodur-PI.pdf **4.** Nagai Y, et al. *Diabetes Technol Ther*. (2013) 15:550–5. **5.** Sartor O. A new form of treatment for prostate cancer. European Urology Supplements. 2006;5:905-910. **6.** Data on File. Tolmar, Inc. **7.** Prettyman J, et. al. *Urologic Nursing*. 2019;39(2):83-99 **8.** Leung AK, Chiu AS, Siu OT, et al. *J R Soc Health*. 1989 Apr;109(2):71-3 **9.** Russo L, Moore WV. *J Clin Endo Metab.* 1982;55(5):1003-6. **10.** Popovic J, et al. *Front Pediatr.* 2022;10:1-12 **11.** Klein K, et al. *J Clin Endo Metab.* 2020;105(10);1-12 **12.** Data on File. Tolmar International Ltd.

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