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

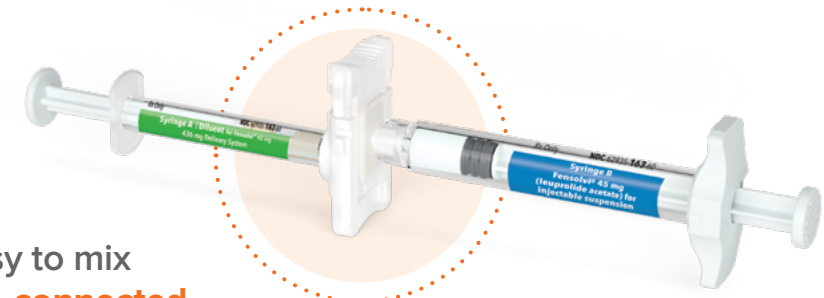
Important Safety Information: FENSOLVI® (leuprolide acetate) for injectable suspension is a gonadotropin releasing hormone (GnRH) agonist used to treat patients 2 years of age and older with central precocious puberty (CPP). CPP may be diagnosed when signs of sexual maturity begin to develop in girls 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 on next page and visit Fensolvi.com/hcp for full Prescribing Information.**

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 gauge

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

Image shows fully-prepped, injection-ready Fensolvi

LH suppression

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

Leuprolide Acetate

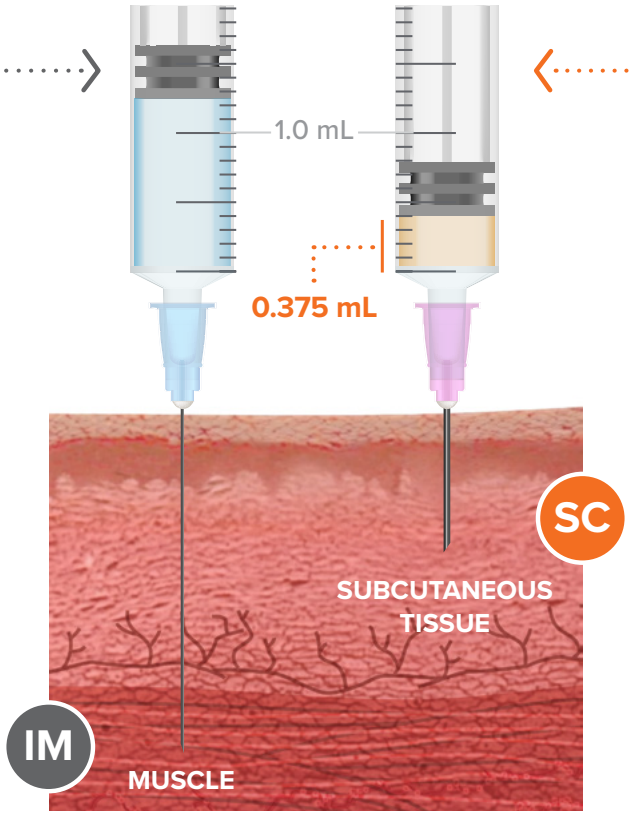
The most commonly prescribed CPP treatment[6]

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. **See additional important Safety Information on next page and visit Fensolvi.com/hcp for full Prescribing Information.**

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. **Visit Fensolvi.com/hcp for full Prescribing Information.**

EFFICACY & SAFETY

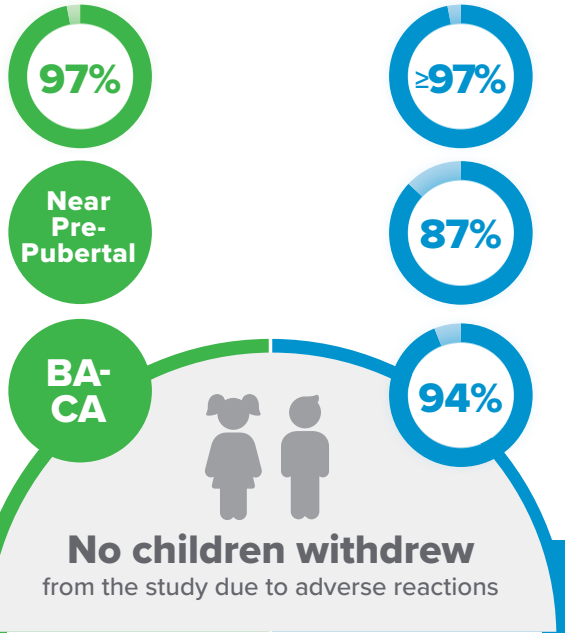
Fensolvi® was proven to be effective and well-tolerated in the pivotal trial

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

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

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

BA = Bone Age; CA = Chronological Age



No children withdrew from the study due to adverse reactions

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

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

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

CLINICAL RESULTS

BIOCHEMICAL RESULTS

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]

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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)

PRODUCT ACCESS

Ordering Fensolvi® has never been easier

There are three ways to obtain Fensolvi

NDC 62935-163-60 (shown on package)
NDC 62935-0163-60 (for billing purposes)
J-CODE J1951

1 Fensolvi TotalSolutions® hub

› Fax patient enrollment form

Fax: 877-991-1798

› Use your current eRx platform

Send a prescription directly to Fensolvi TotalSolutions® via the **Scripts Rx Pharmacy** NPI: 1144730995 | NABP Number: 5922592

Scripts Rx
1815 S Meyers Rd, Suite 100
Oakbrook Terrace, IL 60181

7515 Main St, Suite 180
Houston, TX 77030

Phone: 833-213-9520 | **Fax:** 877-991-1798

2 Specialty distributor

› Order through one of our Specialty Distributor partners

› Bill as you would other office-based injections

3 Integrated specialty pharmacy within your institution

Acquire Fensolvi through your Integrated Specialty Pharmacy (SP) — just like you do for other products

To learn more about easy access — contact a Patient Assistance Reimbursement Manager (PARM) or reach out to your local Tolmar Account Manager

1-888-Fensolvi (1-888-336-7658) | fensolvi@tolmar.com

Fensolvi can be filled by our network of specialty pharmacies

› Specialty Pharmacy Network

CVS Specialty Pharmacy
Kroger Specialty Pharmacy
Maxor Specialty Pharmacy

› Specialty Distribution Partners

Distributors	Fensolvi Item Number
Cardinal Health Specialty	15828934
CuraScript SD	1468789
McKesson Plasma and Biologics	2684389

› Hospital Distribution Partners

Distributors	Fensolvi Item Number
Cencora (formerly Amerisource Bergen)	16020163-60
DCardinal Health	15858014
DHenry Schein	325-0455
McKesson Plasma and Biologics	2684389
Morris & Dickson	555

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PRODUCT ACCESS

Tolmar is committed to providing easy access to Fensolvi®

with enhanced offerings through Fensolvi TotalSolutions® – powered by **Scripts Rx**

Access to Fensolvi has never been easier

- **Our Brand Promise** – All commercially-insured **patients can receive Fensolvi for as little as $5***, regardless of insurance coverage outcome
- The Fensolvi TotalSolutions hub now includes:
  - Comprehensive daily fax report that details case status
  - Direct communication with caregivers via text or phone call
  - Enhanced prior authorization support via the PARx online portal or through Scripts Rx
  - A dedicated team that can access case related information to answer questions in real time

Look inside to see how it works >

fensolvi totalsolutions®

A full line of support services for your practice, your patients & their parents

Office support

- Patient enrollment services
- Benefit investigation
- Case management
- Prior authorization and appeals assistance

Patient support

- Patient enrollment services
- Benefit investigation
- Patient education materials

Financial support

- Copay assistance program
- Patient assistance program

* **FENSOLVI TOTALSOLUTIONS COPAY PROGRAM TERMS AND CONDITIONS** 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 nor 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 two prescriptions per calendar year. The Program assists with the cost of Fensolvi only. It does not assist with the cost of other administrations, medicines, procedures or office visit fees.

Tolmar, 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: https://www.fensolvitotalsolutions.com or call 1-833-213-9520.

Program managed by Scripts Rx on behalf of Tolmar.

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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