

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[®] 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[®] (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 months¹**



› Small injection volume¹
0.375 mL

› Short needle¹
5/8 in.
18G Needle

› Easy to mix
Pre-connected Syringe System



Fensolvi Innovations: Designed With A Child In Mind

Leuprolide Acetate	Subcutaneous Injection	Shortest Needle	Smallest Injection Volume
The most commonly prescribed CPP treatment	PATIENT BENEFIT	FEATURES	
	<ul style="list-style-type: none">Lack of “the-day-after” muscle pain typically associated with IM injection²Reduced risk of hitting bone or nerve²No surgery or product removal required	<ul style="list-style-type: none">5/8 inch needle lengthShorter length may be less likely to cause fear of needle³	<ul style="list-style-type: none">Low injection volume of 0.375 mL¹Smallest injection volume among the GnRHa injectables for CPP¹

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®

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).

Specialty distributor

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

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.

fensolvi
(leuprolide acetate) for injectable suspension

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 months¹**



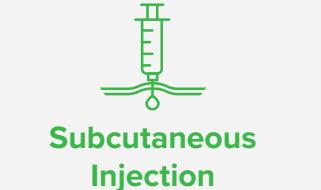
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Fensolvi Innovations: Designed With A Child In Mind



The most
commonly
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treatment

FEATURES



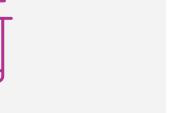
Subcutaneous Injection

- Lack of “the-day-after” muscle pain typically associated with IM injection²
- Reduced risk of hitting bone or nerve²
- No surgery or product removal required



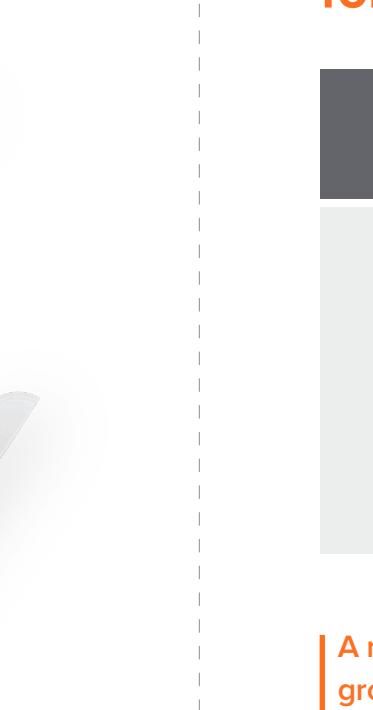
Shortest Needle

- 5/8 inch needle length
- Shorter length may be less likely to cause fear of needle³
- Low injection volume of 0.375 mL¹
- Smallest injection volume among the GnRHa injectables for CPP¹



Smallest Injection Volume

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.



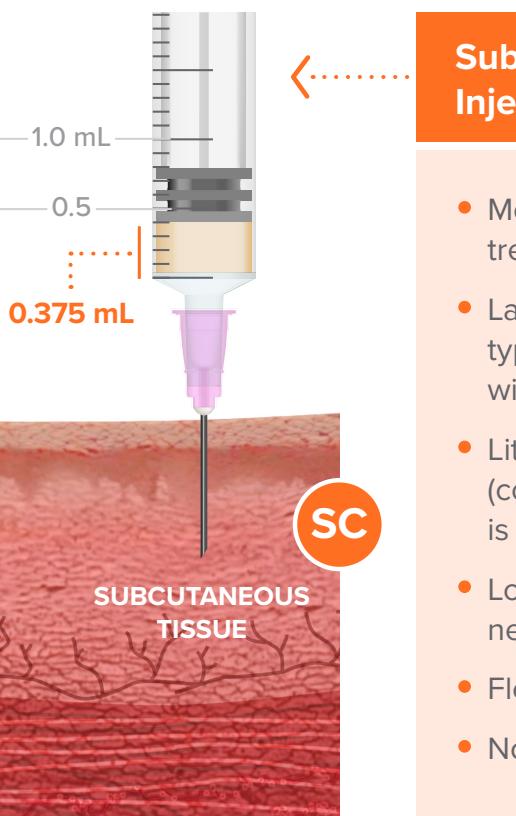
Small injection volume¹

0.375 mL
Short needle¹
5/8 in.
18G Needle

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

Intramuscular Injection (IM)²

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



Subcutaneous Injection (SC)²

- Most recent CPP treatment innovation
- Lack of muscle pain typically associated with IM injections²
- Little muscle mass (common among children) is not a concern²
- Lower risk of bone or nerve damage²
- Flexibility of injection sites²
- 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.⁴



For more information, watch the Fensolvi Product Video

Scan this QR code with your smartphone's camera.



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, 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. **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 treatment⁵

97%

Near Pre-Pubertal

Mean height velocity decreased from Week 4 to Week 48, from 8.9 cm/year to 6.4cm/year¹

BA-CA

Mean difference between BA and CA decreased, from 3 years to 2.7 years¹

BA = Bone Age; CA = Chronological Age

No children withdrew from the study due to adverse reactions

CLINICAL RESULTS

BIOCHEMICAL RESULTS

≥ 77% of girls achieved estradiol suppression to pre-pubertal levels throughout 48 weeks of treatment¹

94%

87% of children achieved peak serum LH of ≤ 5 U/L at week 24¹

87%

Adverse reactions % of patients

Adverse reactions	% of patients
Injection site pain—All injection sites pain was mild to 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%
Hotflash	5% (N=64)

Fensolvi® has a well-established safety and tolerability profile¹

Adverse reactions occurring in ≥5% of patients treated with Fensolvi in an open-label, single-arm trial¹

Other adverse reactions

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

- No adverse reactions led to withdrawal from the study or discontinuation of Fensolvi¹
- Throughout the 12 months of the clinical trial, no serious adverse events or significant adverse events of clinical relevance occurred¹

Learn more at Fensolvi.com/hcp

See full Prescribing Information in Pocket.

At a glance¹

STORAGE Fensolvi[®] 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

Send a prescription directly to Fensolvi TotalSolutions[®] via the **Careform Pharmacy** (NPI 1043762750)

eRX
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 1-412-520-3442
FAX

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

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1. Fensolvi[®] (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[®]

1-866-fensolvi (336-7658)

Specialty Distribution Partners

Specialty Distributors

Fensolvi Item Number

Cardinal Health

5645098

Specialty Distribution

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CuraScript SD

409332

McKesson Specialty

5010287

Distribution

Hospital Distribution Partners

Distributors

Fensolvi Item Number

Amerisource Bergen

10235782

Drug Company

.....

Cardinal Health

5645387

Henry Schein

325-0373

McKesson

1549898

Morris & Dickson

903518