fensolvi®
(leuprolide acetate) for injectable suspension

Keep childhood *Simple*

A Fensolvi product summary

LEARN MORE

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.

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.

Please see additional Important Safety Information on next page and click for full Prescribing Information.

fensolvi® (leuprolide acetate) for injectable suspension

The **first and only** subcutaneous (SC) injection of leuprolide acetate administered twice a year for CPP[1]

Designed with a child in mind

6-MONTHS DOSE

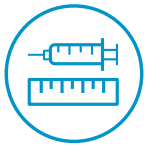
2 injections per year

SMALL INJECTION VOLUME

Low injection volume of 0.375mL

SUBCUTANEOUS INJECTION

No surgery required
Flexibility of multiple injection sites



SHORT NEEDLE

Reduced risk of hitting bone[2]

Fensolvi® efficacy demonstrated through a 12-month, uncontrolled, open-label, single-arm clinical trial

- PRIMARY ENDPOINT: 87% of children had stimulated LH levels <4 IU/L at month 6[1] (N=62)
- At least 97% of girls achieved estradiol suppression to prepubertal level throughout 48 weeks of treatment[3]
- Fensolvi has a favorable safety and tolerability profile
  - No patients withdrew from study due to Adverse Reactions

Please contact your Tolmar representative to schedule a clinical presentation.

IMPORTANT SAFETY INFORMATION

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.

Please see additional Important Safety Information on next page and click for full Prescribing Information.

fensolvi® (leuprolide acetate) for injectable suspension

At a glance[1]

CLASS

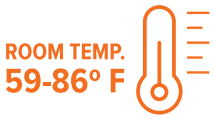
Fensolvi (leuprolide acetate) for injectable suspension, is the **only subcutaneously-delivered leuprolide acetate** in the class of Gonadotropin Releasing Hormone (GnRH) agonists

INDICATION

Fensolvi is indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty

STORAGE

Fensolvi is a refrigerated product. However, once received, it can be **stored at room temperature (59-86°F) for up to 8 weeks**[1]



PACKAGING DIMENSIONS

3” (w) x 5 ½” (h) x 2 ¼” (d)

DOSING FORM

Fensolvi is administered by a health care professional as a **45 mg single injectable suspension** administered subcutaneously once every six months

Injection volume	0.375 mL
Needle length	5⁄8”
Needle gauge	18-gauge

RELEVANT CODES

NDC	NDC 62935-153-50 (shown on package) NDC 62935-0153-50 (for billing purposes)
J-Code J1951	**Descriptions:** Injection, leuprolide acetate for depot suspension, 0.25 mg **Billable Unit:** 0.25 mg; **Units:** 180

IMPORTANT SAFETY INFORMATION

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.

Please see additional Important Safety Information on next page and click for full Prescribing Information.

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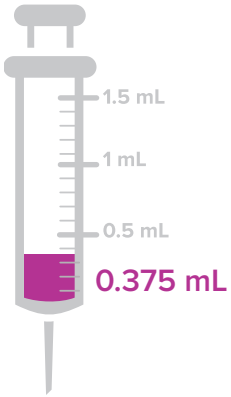
One injection of Fensolvi® was **proven effective for 6 months**[1]

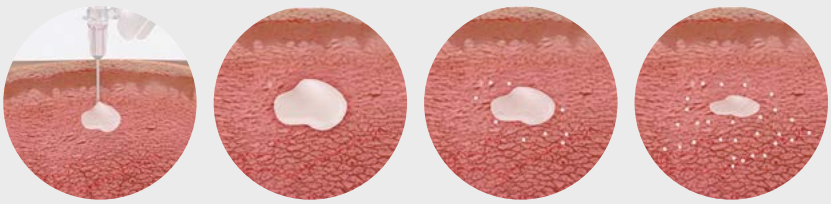
The first and only **subcutaneous** injection with the **lowest volume** of leuprolide acetate available[1]



Fensolvi® delivers leuprolide acetate through a novel, **in-situ polymeric gel extended delivery system**

A single subcutaneous injection delivers 6 months of treatment

The innovative delivery releases leuprolide acetate slowly over time as the polymer dissolves[1]



IMPORTANT SAFETY INFORMATION

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.

Please see additional Important Safety Information on next page and click for full Prescribing Information.

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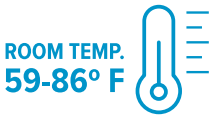
Simple steps for preparation and injection



STEP 1

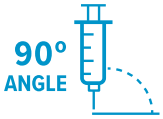
Preparation[1]

Allow the product to reach room temp. before using

STEP 2

Mixing[1]

Thoroughly mix the product for 45 seconds



STEP 3

Administration[1]

Inject Fensolvi® at a 90° angle

For more information, watch the Fensolvi Product Video

Scan this QR code with your smartphone's camera.

For a complete guide on how to correctly prepare, mix and administer Fensolvi, view our mixing video at **www.Fensolvi.com/hcp**

IMPORTANT SAFETY INFORMATION

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.

To report suspected adverse reactions contact Tolmar at 1-844-4TOLMAR (486-5627) or the FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

Please click for additional Important Safety and full Prescribing Information

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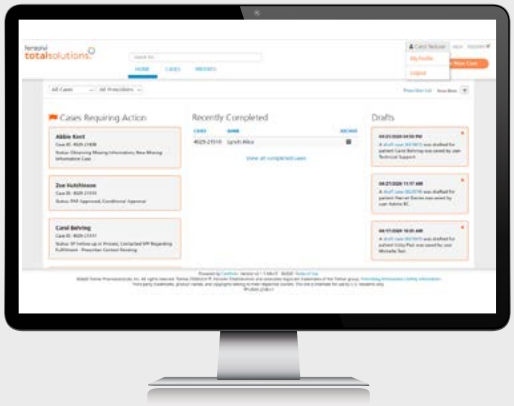
Keeps things simple for your practice, your patients, and their parents

fensolvi totalsolutions™

We offer a full line of patient support services, including:

- Benefit verification
- Assistance with prior authorizations, appeals, and billing and coding inquiries
- Patient education materials
- Co-pay Assistance Program
- Patient Assistance Program



Ordering made easy

For product orders please submit a completed patient enrollment form via fax or through the Fensolvi® portal. For benefit verification inquires and information call:

1-866-FENSOLVI
(1-866-336-7658)
Fax: 1-412-520-3442

www.FensolviTotalSolutions.com

REFERENCES:
1. FENSOLVI® (leuprolide acetate) for injectable suspension 45 mg Prescribing Information. Dublin 2, Ireland: Tolmar International, Ltd.; 2020.
2. Prettyman J, et. al. *Urologic Nursing*. 2019;39(2):83-99.
3. Klein K, et al. *Ped Endo Soc* 2019. Accepted abstract.

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

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