fensolvi®
(leuprolide acetate) for injectable suspension

Keep childhood *Simple*

A Fensolvi product summary

FENSOLVI.COM

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 **2+ YEARS**
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] **ROOM TEMP. 59-86° F**
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 **45 mg INJECTION**
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)
ICD-10	E30.1 (precocious puberty) E22.8 (other hyperfunction of pituitary gland)

For more information, watch the Fensolvi Product Video

Scan this QR code with your smartphone’s camera.

IMPORTANT SAFETY INFORMATION (continued)

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.

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 and enclosed full Prescribing Information in pocket.

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
- → Aligns with office visit schedule

2

SUBCUTANEOUS INJECTION

- → No surgery required
- → Flexibility of multiple injection sites[2]
- → Less risk for hematomas[2]

SMALL INJECTION VOLUME

- → Low injection volume of 0.375mL
- → Child injection experience consideration[2]

SHORT NEEDLE

- → Child injection experience consideration[2]
- → Reduced risk of hitting bone[2]
- → Flexibility of multiple injection sites[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)
- Fensolvi has a favorable safety and tolerability profile

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.

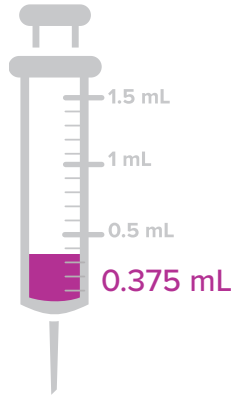
Please see additional Important Safety Information and enclosed full Prescribing Information in pocket.

One injection of Fensolvi® was proven effective for

6 months[1]

The lowest injection volume of leuprolide acetate available[1]

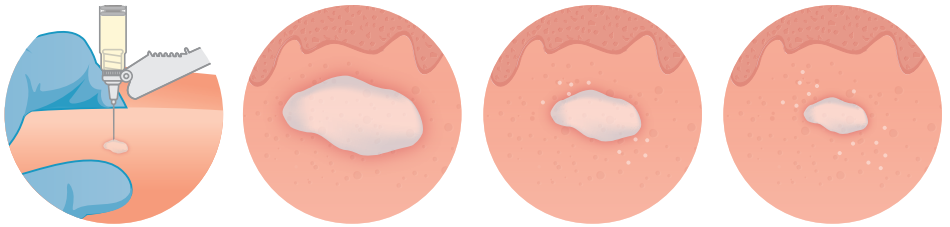
Leuprolide acetate is the most commonly prescribed CPP treatment[3]



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

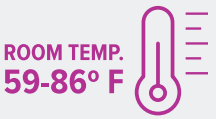
A single subcutaneous injection delivers 6 months of treatment

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



Simple steps for preparation and injection

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



STEP 1

Preparation[1]

Allow the product to reach room temp. before using

STEP 2

Mixing[1]

Thoroughly mix the product for approx. 45 seconds

STEP 3

Administration[1]

Inject Fensolvi® at a 90° angle

IMPORTANT SAFETY INFORMATION (continued)

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.

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.

Please see additional Important Safety Information and enclosed full Prescribing Information in pocket.

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.** IMS Health, Mar 2020.

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

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