

**From:** [Kristen Erikson](#)  
**To:** [AGO - High Cost Prescription Drugs](#)  
**Subject:** New Drug Notice: Fensolvi  
**Date:** Sunday, July 5, 2020 2:44:04 PM  
**Attachments:** [image001.png](#)

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**TO:** [AGO.highcostprescriptiondrugs@vermont.gov](mailto:AGO.highcostprescriptiondrugs@vermont.gov).

**FROM:** Tolmar Pharmaceuticals, Inc

**DATE:** 7/1/2020

**IN RE:** New Drug Notice

To Whom It May Concern,

Please find the following notice in fulfillment of the new drug introduction to market notice requirement pursuant to Code of California Regulations §96075.

NDC: 62935-0153-50	Date of First Sale: 6/5/2020	WAC: \$22,578.00
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While specific marketing and pricing plans are not available in the public domain, generally we market in the US at medical conferences in the pediatric endocrinology community, as well as promoting to appropriate healthcare professionals, patients, and caregivers. Tolmar has a long history of responsible pricing based on several factors including value provided to the patient and the healthcare system, unmet medical need, research and development sustainability, and the competitive environment. The list price of Fensolvi is not reflective of discounts and rebates which may be available to patients and payers including but not limited to, Medicaid and commercial insurance.

Please contact Kristen Erikson for more information.

Regards,

Kristen



Kristen Erikson  
Vice President, *Analytics and Business Operations*  
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Below please find the Important Safety Information ("ISI") and a link to the Package Insert ("PI") for FENSOLVI.

## 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.

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.

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 Full Prescribing Information](#) for additional important safety information.

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](http://www.fda.gov/medwatch).

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