TRIPTODUR® (triptorelin) Product Fact Sheet

Triptodur®
(triptorelin)
for extended release injectable suspension


Actor Portrayal

Triptodur is the first FDA-approved twice-yearly injectable gonadotropin-releasing hormone (GnRH) agonist for Central Precocious Puberty (CPP).

TRIPTODUR is administered as a single IM injection just once every 24 weeks.
TRIPTODUR must only be administered by a healthcare provider.

TRIPTODUR® (triptorelin) for extended-release injectable suspension, for intramuscular (IM) use

INDICATIONS
TRIPTODUR is indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP).

MANUFACTURED BY
Debiopharm Research & Manufacturing SA
Switzerland

MARKETED AND DISTRIBUTED BY
Azurity Pharmaceuticals, Inc., Woburn, MA 01801
Phone: 1-800-461-7449
Websites: **www.azurity.com**
www.Triptodur.com/hcp

PRODUCT NAME
TRIPTODUR

ESTABLISHED NAME
(triptorelin) for extended-release injectable suspension

DOSAGE
One single-dose vial of TRIPTODUR 22.5 mg reconstituted with accompanying diluent (sterile water) 2 mL administered once every 24 weeks

NDC CODE
24338-150-20
22.5 mg single-use kit

HOW TO ORDER
Please see next page for details.

MINIMUM ORDER QUANTITY
One 22.5 mg single-use kit (24338-150-20)

HOW SUPPLIED
One 22.5 mg single-use kit includes:

One single-dose vial of TRIPTODUR 22.5 mg with a Flip-Off seal containing sterile lyophilized white to slightly yellow powder cake

One sterile glass syringe with Luer Lock prefilled with 2 mL of diluent (sterile water) for injection

Two sterile 21-gauge, 1½" needles (*thin-wall*) with safety cover

One Package Insert

Patient Information and Medication Guide

DATED ITEMS
The expiration date is printed on each single-use kit.

PRESCRIPTION LEGEND
Prescription only. TRIPTODUR must be administered under the supervision of a physician.

STORAGE REQUIREMENTS
Store at 20°C to 25°C (68°F-77°F)
[See USP Controlled Room Temperature]
Do not freeze.

PRODUCT INFORMATION
For medical information:
Phone: 1-800-461-7449
Email: medical.information@azurity.com

To report an adverse event:

FDA
Phone: 1-800-FDA-1088
(1-800-332-1088)
Website: www.fda.gov/medwatch

Product labeling, packaging, and imagery are for representation purposes only.

IMPORTANT SAFETY INFORMATION FOR TRIPTODUR (triptorelin) for extended-release injectable suspension

INDICATIONS
TRIPTODUR is indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP).

IMPORTANT SAFETY INFORMATION

Contraindications

TRIPTODUR is contraindicated in:

- Individuals with a known hypersensitivity to triptorelin or any other component of the product, or other GnRH agonists or GnRH.
- Women who are or may become pregnant. Expected hormonal changes that occur with TRIPTODUR treatment increase the risk for pregnancy loss and fetal harm when administered to a pregnant woman. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be advised of the potential risk to the fetus.

Please see the Important Safety Information continued in piece, and the full accompanying Prescribing Information.

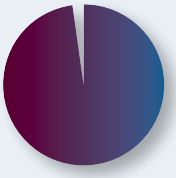
TRIPTODUR® (triptorelin) Product Fact Sheet

Triptodur®
(triptorelin)
for extended release injectable suspension

AN EFFECTIVE TREATMENT[2]

IN A PHASE 3 CLINICAL TRIAL

93%
of patients receiving Triptodur had their luteinizing hormone (LH) suppressed to prepubertal levels at month 6 (primary endpoint).[2]



98%
of patients maintained these levels at 12 months.[2]

Study was conducted in 44 patients (n=39 girls; n=5 boys) with CPP aged 2 to 9 years who were naive to previous GnRHa treatment.[2]

Primary efficacy endpoint: Percentage of children with serum LH suppression to prepubertal levels (serum LH ≤5 IU/L thirty minutes after GnRHa stimulation) at month 6.[2]

In clinical trials for TRIPTODUR, the most common adverse reactions (≥4.5%) are injection site reactions, menstrual (vaginal) bleeding, hot flush, headache, cough, and infections (bronchitis, gastroenteritis, influenza, nasopharyngitis, otitis externa, pharyngitis, sinusitis, and upper respiratory tract infection).[1]

HOW TO ORDER

TRIPTODUR is available through select specialty distributors. Please see ordering information below.

NDC Code	Permanent J-Code	Descriptor	Billing Unit Conversion	Amerisource Bergen (ASD/Besse)	Cardinal	McKesson	Morris & Dickson (MDSD)
24338-150-20	**J3316**	injection, triptorelin extended release, 3.75 mg	3.75 mg = 1 unit **Single-Use Kit 22.5 mg = 6 Units**	Available	Available	Available	Available

TRIPTODUR COPAY ASSISTANCE PROGRAM

Eligible patients may pay as little as **$5**.* **95%** of commercially insured eligible patients* using the Triptodur Copay Assistance Program **paid $5 for Triptodur**.[2] Please call the Triptodur Care Program for assistance (833)-401-CARE (2273) M-F.

*Please visit https://triptodur.com/hcp/care-program/ for Terms and Conditions.

IMPORTANT SAFETY INFORMATION FOR TRIPTODUR (continued)

Warnings and Precautions

Initial Rise of Gonadotropins and Sex Steroid Levels – During the early phase of therapy, gonadotropins and sex steroids rise above baseline because of the initial stimulatory effect of the drug. Therefore, a transient increase in clinical signs and symptoms of puberty, including vaginal bleeding, may be observed during the first weeks of therapy or after subsequent doses.

Psychiatric Events – Psychiatric events have been reported in patients taking GnRH agonists. Postmarketing reports with this class of drugs include symptoms of emotional lability, such as crying, irritability, impatience, anger, and aggression. Monitor for development or worsening of psychiatric symptoms during treatment with TRIPTODUR.

Convulsions – Postmarketing reports of convulsions have been observed in patients receiving GnRH agonists, including triptorelin. These included patients with a history of seizures, epilepsy, cerebrovascular disorders, central nervous system anomalies or tumors, and patients on concomitant medications that have been associated with convulsions such as bupropion and SSRIs. Convulsions have also been reported in patients in the absence of any of the conditions mentioned above.

Pseudotumor Cerebri (idiopathic intracranial hypertension) - has been reported in pediatric patients receiving GnRH agonists, including triptorelin. Monitor patients for signs and symptoms of pseudotumor cerebri, including headache, papilledema, blurred vision, diplopia, loss of vision, pain behind the eye or pain with eye movement, tinnitus, dizziness, and nausea.

Adverse Reactions

In clinical trials for TRIPTODUR, the most common adverse reactions (≥4.5%) are injection site reactions, menstrual (vaginal) bleeding, hot flush, headache, cough, and infections (bronchitis, gastroenteritis, influenza, nasopharyngitis, otitis externa, pharyngitis, sinusitis, and upper respiratory tract infection).

You are encouraged to report side effects of prescription drugs to Azurity Pharmaceuticals, Inc. at 1-800-461-7449, or to the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

The Important Safety Information does not include all the information needed to use TRIPTODUR safely and effectively. For additional safety information, please consult the full Prescribing Information for TRIPTODUR.

Reference: 1. Triptodur [package insert]. Woburn, MA 01801: Azurity Pharmaceuticals, Inc. 2023. **2.** Data on file. Azurity Pharmaceuticals, Inc. 2023.

azurity® pharmaceuticals