Triptodur (triptorelin)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Triptodur
- **Generic name:** Triptorelin pamoate
- **Pharmacological class:** GnRH agonist
- **Strength and Formulation:** 22.5mg; lyophilized microgranules for ext-rel IM inj after reconstitution; contains mannitol
- **Manufacturer:** Arbor Pharmaceuticals
- **How supplied:** Single-use kit—1
- **Legal Classification:** Rx

Indications

- Treatment of central precocious puberty

Dosage & Administration

- Give as IM inj in buttock or thigh
- Children
  - <2yrs: not established
  - ≥2yrs: 22.5mg once every 24 weeks
- Discontinue at appropriate time point for onset of puberty
- Consider switching to alternative GnRH agonist if Triptodur dose is inadequate

Considerations for Special Populations

- **Adults:** Not applicable
- **Pediatric:** <2yrs: not established
- **Pregnancy:** See Contraindications
- **Nursing mothers:** No data on presence of triptorelin in human milk
- **Renal impairment:** not studied
- **Hepatic impairment:** not studied

Contraindications

- Pregnancy

Warnings/Precautions

- Use aseptic technique
- Must administer under physician supervision
- Initial transient rise in gonadotropins and sex steroids may result in increased signs/symptoms of puberty
- Monitor **LH and sex steroid levels** at 1–2 months after treatment initiation, during, and with each subsequent dose

Warnings/Precautions

- Assess **height** every 3–6 months and bone age periodically
- Monitor for psychiatric symptoms
- History of seizures/epilepsy, cerebrovascular disorders, CNS anomalies or tumors: risk of **convulsions**
- Renal or hepatic impairment
- Discontinue if overdosage occurs

Interactions

- Concomitant **hyperprolactinemic drugs**: not recommended
- Caution with concomitant drugs that are associated with **convulsions** (eg, bupropion, SSRIs)
- May interfere with pituitary gonadotropic and gonadal function tests

Adverse Reactions

- Inj site reactions
- Menstrual bleeding
- Hot flush
- Headache
- Cough
- Infections
- Psychiatric events
- Convulsions

Mechanism of Action

- Triptorelin is a GnRH agonist
- After the first administration, there is a transient surge in circulating levels of LH, FSH, testosterone, and estradiol
- After chronic and continuous administration, there is a sustained decrease in LH/FSH secretion, and marked reduction in sex steroids

Clinical Studies

- Triptodur was examined in a single-arm, open-label study (n=44) of children aged 2 to 9 years with central precocious puberty
  - All were naïve to previous GnRH agonist treatment
- Patients were given Triptodur 22.5mg at an interval of 24 weeks
  - Evaluated for a total of 12 months

Clinical Studies

- Triptodur suppressed pituitary release of LH and FSH, and gonadal secretion of estradiol (girls) and testosterone (boys)
- For all timepoints, ≥93% of children achieved LH suppression to prepubertal levels
  - **≥79%** of girls achieved prepubertal levels of estradiol (<20pg/mL)
  - **≥80%** of boys achieved prepubertal levels of testosterone (<30ng/dL)

Clinical Studies

- Triptodur stopped or reversed progression of clinical signs of puberty
  - **95%** of children showed no increase in bone age/chronological age ratio
  - **89%** of children showed stabilization of sexual maturation at Month 12

Clinical Studies

- After the second Triptodur injection, all girls were assessed for evidence of acute-on-chronic phenomenon (basal LH increase >5 IU/L or serum estradiol level >20pg/mL 48hrs post-injection)
  - Only 1 girl showed biochemical evidence of acute-on-chronic phenomenon
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/triptodur/drug/34764/