1. Use appropriate aseptic technique for preparation and administration.
   • To minimize the risk of needle blockage during the injection, ensure that the Triptodur suspension will sediment very quickly and should be injected in a sterile manner.
   - The injection of the suspension should be performed rapidly and is best and unpremedicated in order to avoid any potential blockage of the needle.

2. Dosage and Administration
   1.**TRIPTODUR** (triptorelin) for extended-release injectable suspension, a white to slightly yellow powder cake in a single-dose vial for reconstitution with the water diluent syringe with a push and clockwise twist. This 21-gauge needle will only be used for reconstitution of the product.

   a. Remove the plastic tip from the vial. Slightly exceed the stopper of the 21-gauge needle. Then pull the dose needle shaft from the vial.

   b. Insert the 21-gauge needle through the stopper into the sterile vial to the line. Exercising the plunger of the syringe as the plunger.

   c. Once the vial is mixed, proceed to the next steps and administer without delay.

   d. If the suspension does not appear milky and homogeneous without any visible aggregates or precipitates.

3. Contraindications
   - Must only be administered by a healthcare provider.

4. Dosage and Administration
   - Initial dose of 1 mg of a new patient and 1 mg every 28 days in patients on chronic therapy, unless increased to 2 mg every 28 days if adequate response is not observed.
   - Monitoring: Monitor responses to TRIPTODUR with LHRH agonist or antagonist in dose-response manner, including increased risk of hyperprolactinemia.

5. Administration
   - Insert and advance the needle hub to the center of the needle hub of the Motorola Mining Cartridge up to the line. The complete and homogeneous (milky) suspension of the product may require up to 60 seconds of agitation.
TRIPTODUR is indicated for the treatment of children with central precocious puberty (CPP). Following the first administration, there is a transient surge in circulating levels of LH, which peaks 4 hours postdose with a geometric mean Cmax of 39.9 and 36.5 ng/mL, intramuscular injection 24 weeks later in children 2 to 9 years old with CPP, triptorelin 22.5 mg was given as a single intramuscular injection. Studies have shown that when administered as a single injection every 6 months, patients 2 years of age and older based on a single-arm open-label study of patients 2 years of age and older. The mechanism of action of triptorelin (patient anuric, Cl(creat) = 0) was 76.2 mL/min, thus indicating that the formulation is appropriate for the intramuscular route of administration. The formula of triptorelin pamoate is 5-oxo-L-prolyl-L-histidyl-L-tryptophyl-L-seryl-L-tyrosyl-naturally occurring gonadotropin-releasing hormone (GnRH or LHRH). The chemical name of triptorelin pamoate is C29H38N2O5. Preclinical studies in animals have shown that triptorelin suppresses gonadal secretion of estradiol in girls and testosterone in boys (Table 3). At all timepoints evaluated, ≥93% of children achieved LH suppression to prepubertal levels (4.5 and 5.5 ng/mL for boys and girls, respectively). Following the second TRIPTODUR injection, 22 children (all girls) were assessed for clinical and biochemical endpoints:

- Sexual maturation:
  - Endpoint % (n/N) of children achieving endpoint
  - Time of achievement:
  - LH (mIU/mL) 89%
  - Estradiol (ng/dL) 77%
  - Testosterone (ng/dL) 89%

- Pain:
  - Pain perception:
  - Pain severity:
  - Pain score:
  - Pain intensity:
  - Pain duration:

- Adverse reactions:
  - Worsening emotional symptoms while taking TRIPTODUR.
  - Convulsions
  - Seizures have also happened in people who have not had any of these problems.

TRIPTODUR is contraindicated in pregnancy. If the patient becomes pregnant while receiving TRIPTODUR, the child should be observed for the development of sexual precocity. TRIPTODUR is a registered trademark of Debiopharm International SA.

### Side Effects

*GnRH agonists* medicines including TRIPTODUR. No studies were conducted to assess the effect of triptorelin on male fertility.

### Patent

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