Triptodur® (triptorelin) Administration

Triptodur®
(triptorelin)
for extended release injectable suspension

Actor portrayal.

TRIPTODUR® (triptorelin) ADMINISTRATION BOOKLET

Important information for administering Triptodur, including helpful tips.

Triptodur (triptorelin) is the first FDA-approved twice yearly intramuscular (IM) injection for the treatment of central precocious puberty (CPP).[1] For full reconstitution and administration instructions, please read this booklet in its entirety, as well as the Prescribing Information in full, prior to administering Triptodur. For best results, here are some helpful tips for proper administration:

- Triptodur must only be administered by a healthcare professional.
- Triptodur must only be administered with a thin-wall 21-gauge needle.
- 30-60 SEC — When reconstituting the product in the vial, thoroughly mix with agitation for 30 to 60 seconds, ensuring the diluent rinses the sides of the vial.
- If the suspension appears milky and homogeneous without visible aggregates or precipitates, administer the suspension immediately.
- ! — To minimize the risk of needle blockage during the injection, ensure that the preparation of the injection is not interrupted and/or the mixed suspension syringe is not put aside because the suspension will sediment quickly.

This booklet is not intended as a complete description of the benefits and risks related to the use of Triptodur. Please refer to the enclosed full Prescribing Information for more information.

If you have any questions about the information in this booklet or the safe and effective use of Triptodur, please contact our medical information department at 1-800-461-7449 or at medical.information@azurity.com.

Reference: 1. Triptodur [package insert]. Woburn, MA: Azurity Pharmaceuticals, Inc. 2023.

IMPORTANT SAFETY INFORMATION
INDICATION
TRIPTODUR is indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP).
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 additional Important Safety Information throughout and on page 9 and accompanying Full Prescribing Information.

Triptodur® (triptorelin) for extended release injectable suspension

RECONSTITUTION AND ADMINISTRATION INSTRUCTIONS FOR TRIPTODUR®

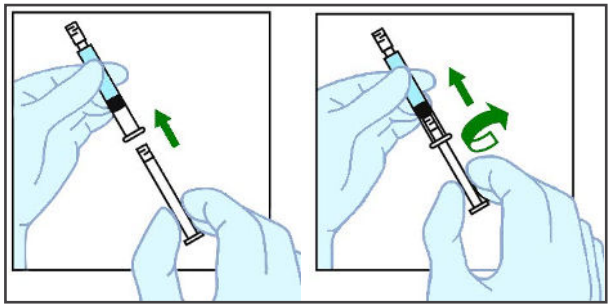
Triptodur is administered as a single intramuscular (IM) injection just once every 24 weeks.

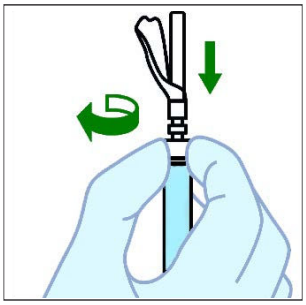
! Read these instructions completely before you begin.

- **Triptodur suspension will sediment very quickly and should be injected immediately after reconstitution in accordance with the detailed instructions below.**
- **If the sequence of steps to prepare the suspension is interrupted and/or the vial is put aside, the suspension will start to separate into diluent and microgranules.**
- **To minimize the risk of needle blockage during the injection, ensure that the preparation of the injection is not interrupted and/or the mixed suspension syringe is not put aside because the suspension will sediment quickly.**

STEP 1 Prepare the prefilled water diluent syringe for reconstitution

- Use appropriate aseptic technique for preparation and administration.
- Screw the plunger rod into the barrel end of the prefilled sterile water diluent syringe.
- To remove the cap, twist counterclockwise to separate from the Luer lock on the syringe barrel.
- **Firmly attach** one of the 21-gauge sterile safety needles onto the prefilled sterile water diluent syringe with a push and clockwise twist. This 21-gauge needle will only be used for reconstitution of the product.





IMPORTANT SAFETY INFORMATION (Cont.)

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.

Please see additional Important Safety Information throughout and on page 9 and accompanying Full Prescribing Information.

Triptodur®
(triptorelin)
for extended release injectable suspension

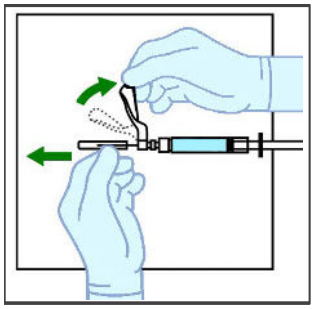
RECONSTITUTION AND ADMINISTRATION INSTRUCTIONS FOR TRIPTODUR®

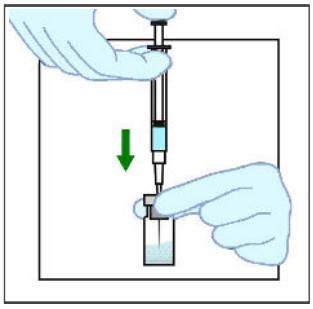
Please read all of the steps and instructions below before you begin the administration of Triptodur.

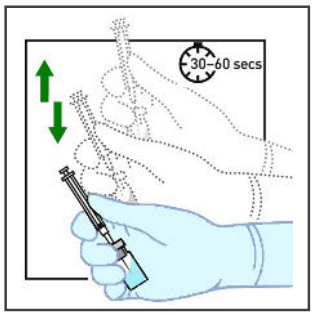
STEP 2 Inject the Sterile Water diluent into the vial, ensuring the diluent rinses the sides of the vial

- Remove the plastic Flip-off from the vial. Disinfect the visible part of the stopper.
- Pull back on the safety cover towards the syringe and away from the 21-gauge needle. Then pull the clear needle shield off.

- Insert the 21-gauge needle through the stopper. Inject the sterile water diluent into the vial, ensuring the diluent rinses the sides of the vial. Do not release the plunger rod.
- If the syringe plunger is not maintained in position, it will naturally withdraw product into the syringe. Thoroughly mix the vial with agitation for 30 to 60 seconds, ensuring the diluent rinses the sides of the vial.







IMPORTANT SAFETY INFORMATION (Cont.)

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.

Please see additional Important Safety Information throughout and on page 9 and accompanying Full Prescribing Information.

Triptodur®
(triptorelin)
for extended release injectable suspension

RECONSTITUTION AND ADMINISTRATION INSTRUCTIONS FOR TRIPTODUR®

Please read all of the steps and instructions below before you begin the administration of Triptodur.

STEP 2 Inject the water diluent into the vial and reconstitute the solution (Cont.)

Before moving on to the next step, check visually that the suspension appears milky and homogeneous without any visible aggregates or precipitates.

- If the suspension DOES NOT appear milky and homogeneous without any visible aggregates or precipitates, continue with the agitation. An up and down agitation can also be used to help eliminate aggregates or precipitates. The complete and homogeneous (milky) suspension of the product may require up to 60 seconds of agitation.

Important: Once mixed, proceed to the next steps and administer without delay.

- The suspension will sediment very quickly so it is imperative to withdraw the suspension into the syringe directly after suspending the product in the vial.

Milky and homogeneous suspension

Visible sedimentation, aggregates and precipitates in suspension, continue with an up and down agitation until the suspension appears milky and homogeneous

IMPORTANT SAFETY INFORMATION (Cont.)

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.

Please see additional Important Safety Information throughout and on page 9 and accompanying Full Prescribing Information.

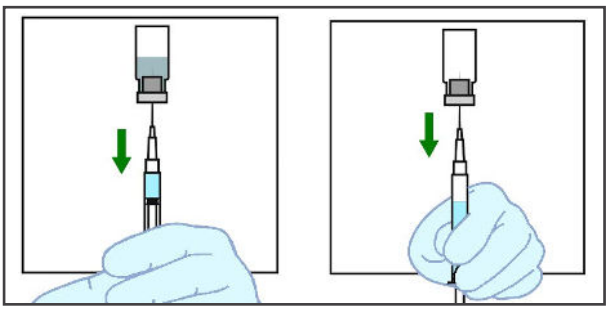
Triptodur® (triptorelin) for extended release injectable suspension

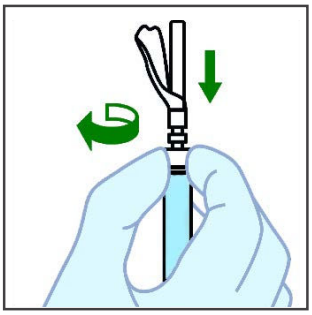
RECONSTITUTION AND ADMINISTRATION INSTRUCTIONS FOR TRIPTODUR®

Please read all of the steps and instructions below before you begin the administration of Triptodur.

STEP 3 Withdraw suspension into the syringe

- Invert the vial and move back the syringe in order to position the end of the 21-gauge needle very near the level of the stopper, making sure the needle lumen is still completely in the vial.
- Pull back the plunger rod slowly to withdraw the reconstituted product into the syringe, withdrawing as much of the reconstituted product into the syringe as possible. Move the tip of the needle at the level of the stopper so as to be able to withdraw a maximum amount of suspension.
- Withdraw the needle from the vial and push the safety cover forward toward the needle until you hear and/or feel it lock. Then remove the first 21-gauge needle by grasping the needle hub to disconnect the needle from the syringe and discard it. **This (first) 21-gauge needle will no longer be used.**





IMPORTANT SAFETY INFORMATION (Cont.)
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.

Please see additional Important Safety Information throughout and on page 9 and accompanying Full Prescribing Information.

Triptodur®
(triptorelin)
for extended release injectable suspension

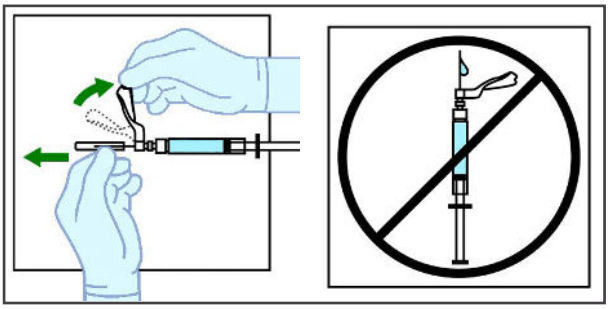
RECONSTITUTION AND ADMINISTRATION INSTRUCTIONS FOR TRIPTODUR®

Please read all of the steps and instructions below before you begin the administration of Triptodur.

STEP 4 Administer suspension

To minimize the risk of needle blockage during the injection, ensure that the preparation of the injection is not interrupted and/or the mixed suspension syringe is not put aside because the suspension will sediment quickly.

- **Firmly attach the second sterile needle** onto the syringe with a push and clockwise twist and pull back the safety cover towards the syringe. This 21-gauge needle will be used for administration. Triptodur must **only** be administered with a thin-wall 21-gauge needle.
- Do not prime the needle. Inspect the suspension visually for particulate matter and discoloration.
    - **If the suspension does not appear milky and homogeneous, continue with up and down agitation.**
    - **If the suspension appears milky and homogeneous without visible aggregates or precipitates, administer the suspension immediately.**



Milky and homogeneous suspension

Visible sedimentation, aggregates and precipitates in suspension, continue with an up and down agitation until the suspension appears milky and homogeneous

IMPORTANT SAFETY INFORMATION (Cont.)
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).

To report SUSPECTED ADVERSE REACTIONS, contact Azurity Pharmaceuticals, Inc. at 1-800-461-7449, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see additional Important Safety Information throughout and on page 9 and accompanying Full Prescribing Information.

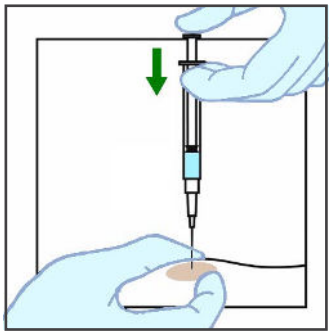
Triptodur®
(triptorelin)
for extended release injectable suspension

RECONSTITUTION AND ADMINISTRATION INSTRUCTIONS FOR TRIPTODUR®

Please read all of the steps and instructions below before you begin the administration of Triptodur.

STEP 4 Administer suspension (Cont.)

- Inject the patient intramuscularly, preferably in either buttock or thigh, using the entire contents of the syringe. The injection of the suspension should be performed rapidly and in a steady and uninterrupted manner in order to avoid any potential blockage of the needle.
- After administering the injection, immediately activate the safety cover.



Disposal

- Center your thumb or forefinger on the textured finger pad area of the safety cover and push it forward over the needle until you hear or feel it lock.
- Use the one-handed technique and activate the mechanism away from yourself and others.
- Immediately discard the syringe assembly into a suitable sharps container.

Please see additional Important Safety Information throughout and on page 9 and accompanying Full Prescribing Information.

Triptodur®
(triptorelin)
for extended release injectable suspension

IMPORTANT SAFETY INFORMATION FOR TRIPTODUR

INDICATION

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.

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).

To report SUSPECTED ADVERSE REACTIONS, contact Azurity Pharmaceuticals, Inc. at 1-800-461-7449, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

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.

Notes:

Notes:

CHECK – INSPECT – INJECT

Triptodur® (triptorelin) Administration

CHECK

Check to ensure the patient and injection site is prepared. One of the provided thin-wall 21-gauge needles is only used for reconstitution of the product, and the other one is used for administration. Make sure the syringe plunger is maintained in position when mixing the suspension in the vial. If the suspension DOES NOT appear milky and homogenous without any visible aggregates or precipitates agitate vial for 60 seconds.

INSPECT

Once the reconstituted suspension is mixed thoroughly it should appear milky and homogeneous without any visible aggregates or precipitates. To minimize the risk of needle blockage during the injection, ensure that the preparation of the injection is not interrupted and/or the mixed suspension syringe is not put aside because the suspension will sediment quickly.

Important: Once mixed, proceed to the next steps and administer without delay.

INJECT

Using the first needle, withdraw the milky and homogeneous suspension into the syringe. Discard needle. Firmly attach the *second* sterile needle onto the syringe with a push and clockwise twist and pull back the safety cover towards the syringe.

Do not prime the needle. Inspect the suspension visually for particulate matter and discoloration. Inject the patient intramuscularly, preferably in either buttock or thigh using the entire contents of the syringe. The injection of the suspension should be performed rapidly and in a steady and uninterrupted manner in order to avoid any potential blockage of the needle.

Triptodur must **only** be administered with a thin-wall 21-gauge needle.

Please see enclosed Full Prescribing Information.
For additional info visit www.Triptodur.com/hcp.

azurity® pharmaceuticals