Triptodur® (triptorelin) Reconstitution and Administration Guide

Triptodur® is the first FDA-approved twice-yearly intramuscular (IM) injection gonadotropin releasing hormone (GnRH) agonist.

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).

Please see additional Important Safety Information on pages 13 and 14 and full Prescribing Information.

Triptodur® (triptorelin) Administration Booklet

The dosage of Triptodur is 22.5 mg reconstituted with accompanying diluent (sterile water) 2 mL, administered as a single IM injection just once every 24 weeks.

For full reconstitution and administration instructions, please read this booklet in its entirety, as well as the Prescribing Information, 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**
- **Check that the patient and injection site are ready before reconstituting Triptodur, so that you can reconstitute and administer without delay**
- **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 full Prescribing Information for more information.

Please see Important Safety Information on pages 13 and 14 and full Prescribing Information.

Read these instructions completely before you begin.

Triptodur®
(triptorelin)
for extended release injectable suspension

For a smoother administration process, remember, don't stop, don't wait, don't prime!

Don't stop!

- Once reconstituted, **if the suspension appears milky and homogeneous without visible aggregates or precipitates, administer the suspension immediately**
- If the suspension **DOES NOT** appear milky and homogeneous without any visible aggregates or precipitates, simply continue with the agitation until it is milky and homogeneous

Don't wait!

- **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**

Don't prime!

- To help minimize risk of needle blockage during the injection, **do not prime the needle**

Before you begin

Check that the patient and injection site are ready

To ensure that you can prepare and administer Triptodur without interruptions or delays, be sure that the patient and injection site are ready before proceeding to the next steps.

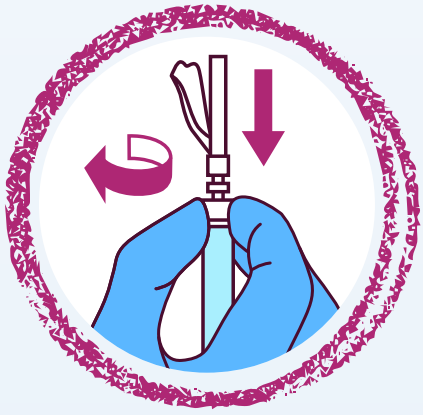
Please see Important Safety Information on pages 13 and 14 and full Prescribing Information.

STEP 1 PREPARE THE PREFILLED STERILE WATER DILUENT SYRINGE

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.

- **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.



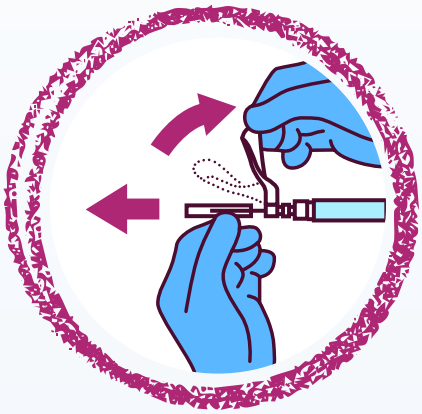
Please see Important Safety Information on pages 13 and 14 and full Prescribing Information.

STEP 2 RECONSTITUTE THE SUSPENSION

Prepare the suspension

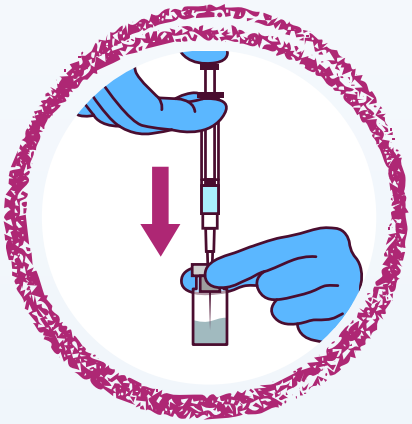
Remove the plastic flip-off from the vial. Disinfect the visible part of the stopper.

Pull back on the safety cover towards the syringe and away from the 21-gauge needle. Then pull the clear needle shield off.

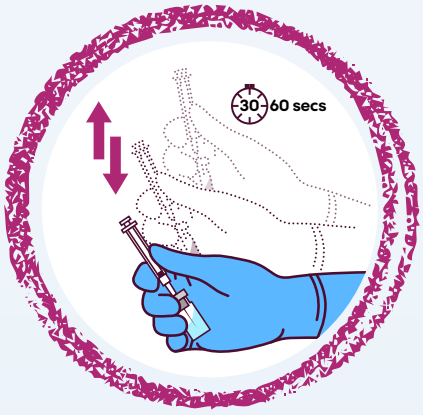


Insert the 21-gauge needle through the stopper and inject the sterile water diluent into the vial, ensuring the diluent rinses the sides of the vial.

- **Do not release the plunger rod** because it will naturally withdraw product back into the syringe if not maintained in position



Thoroughly mix the vial with agitation for **30 to 60 seconds,** ensuring the diluent rinses the sides of the vial. The suspension should appear milky and homogeneous when done mixing.



Please see Important Safety Information on pages 13 and 14 and full Prescribing Information.

STEP 2 RECONSTITUTE THE SUSPENSION *(continued)*

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

Inspect the reconstituted product

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.

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.**

Product labeling, packaging, and imagery are for representation purposes only and shall constitute the property of Azurity.

Don't stop!

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

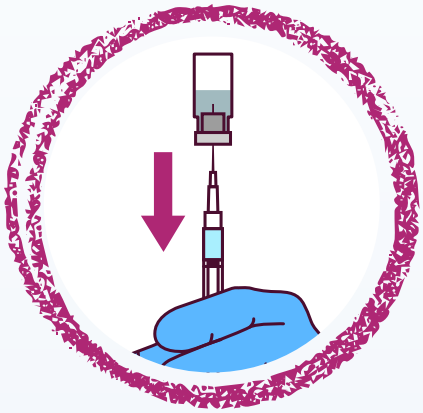
The suspension will sediment very quickly so it is imperative to withdraw the suspension into the syringe directly after suspending the product in the vial

Please see Important Safety Information on pages 13 and 14 and full Prescribing Information.

STEP 3 WITHDRAW THE SUSPENSION

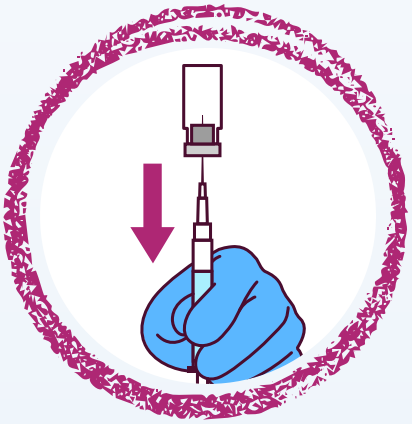
Withdraw the suspension into the syringe

Invert the vial and move the syringe back in order to position the end of the 21-gauge needle 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



Here's a pro tip

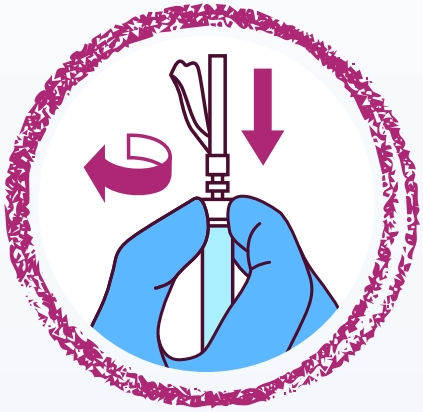
When you withdraw the reconstituted product into the syringe, leave a little gap in the syringe between the medication and the hub. This space lets you continue to agitate the medication in the syringe right up until you inject.

Please see Important Safety Information on pages 13 and 14 and full Prescribing Information.

STEP 3 WITHDRAW THE SUSPENSION *(continued)*

Remove first 21-gauge needle

Withdraw the needle from the vial and push the safety cover forward toward the needle **until you hear and/or feel it lock.**



- **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**

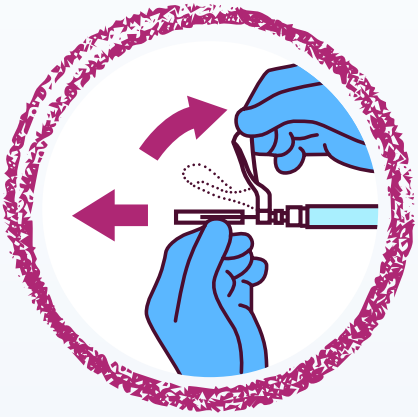
Please see Important Safety Information on pages 13 and 14 and full Prescribing Information.

STEP 4 ADMINISTER THE SUSPENSION

Attach second needle (don't prime!)

Firmly attach the second sterile needle onto the syringe with a push and clockwise twist, and pull back the safety cover

- This 21-gauge needle will be used for administration. Triptodur must **only** be administered with a thin-wall 21-gauge needle



To help minimize risk of needle blockage during the injection, **do not prime the needle**

Please see Important Safety Information on pages 13 and 14 and full Prescribing Information.

STEP 4 ADMINISTER THE SUSPENSION *(continued)*

Inspect the suspension

Inspect the suspension visually for particulate matter and discoloration

- **If the suspension appears milky and homogeneous without visible aggregates or precipitates, administer the suspension immediately**
- **If the suspension DOES NOT appear milky and homogeneous, continue with up and down agitation until the suspension appears milky and homogeneous**

Milky and homogeneous suspension.

Visible sedimentation, aggregates, and precipitates in suspension.

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Don't wait!

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

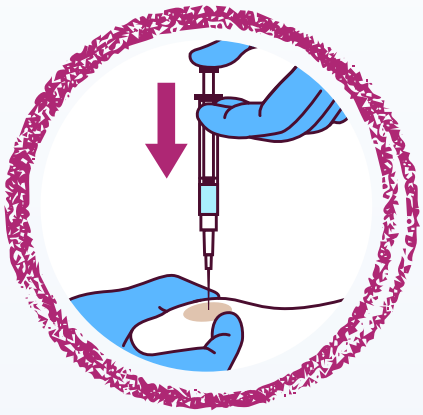
Please see Important Safety Information on pages 13 and 14 and full Prescribing Information.

STEP 4 ADMINISTER THE SUSPENSION *(continued)*

Administer without delay

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



Dispose of syringe assembly

After administering the injection, immediately activate the safety cover.

- 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 Important Safety Information on pages 13 and 14 and full Prescribing Information.

ADMINISTER TRIPTODUR WITH CONFIDENCE

Additional Support and Guidance for Triptodur Reconstitution and Administration Is Available Here!

Scan the QR code to watch the **Triptodur Reconstitution and Administration video.**

Visit www.Triptodur.com/hcp to request live or virtual in-service support and training for Triptodur reconstitution and administration.

Triptodur must only be administered by a healthcare professional. Prior to administering Triptodur, it is important that you connect with your local Triptodur representative to review the reconstitution and administration steps. This will help support a positive patient experience.

Please see Important Safety Information on pages 13 and 14 and full Prescribing Information.

IMPORTANT SAFETY INFORMATION FOR TRIPTODUR

Triptodur® (triptorelin) for extended release injectable suspension

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.

IMPORTANT SAFETY INFORMATION FOR TRIPTODUR *(continued)*

Triptodur® (triptorelin) for extended release injectable suspension

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.

Triptodur® (triptorelin) Administration

CHECK. INSPECT. INJECT.

Triptodur® (triptorelin) for extended release injectable suspension

CHECK

Check to ensure the patient and injection site are prepared and ready. Before moving on to the next step, visually **check** that the reconstituted suspension in the vial appears milky and homogeneous without any visible aggregates or precipitates.

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.

INSPECT

Inspect the reconstituted suspension. When mixed thoroughly, it **should appear 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 an up and down agitation for up to 60 seconds.

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 and pull back the safety cover towards the syringe.

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.

Do not prime the needle. Inspect the suspension visually for particulate matter and discoloration. If the suspension appears milky and homogeneous without visible aggregates or precipitates, immediately 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.

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