



#### **FOR PARENTS**

# About TRIPTODUR® (triptorelin) for extended release injectable suspension: A Treatment For Central Precocious Puberty (CPP)

Triptodur is an injectable prescription medicine used for the treatment of children 2 years of age or older with central precocious puberty (CPP). It is administered as a single intramuscular (IM) injection just once every 24 weeks, making it the first FDA-approved medicine for CPP to offer once-every-sixmonths dosing. Treatment with Triptodur does not require surgery.

Treatments for CPP weaken the effects of GnRH signaling on the pituitary gland, reducing the release of hormones that cause puberty. By stopping the signaling of these hormones, the puberty process will be delayed until the end of the treatment. The effect of Triptodur on pituitary and gonadal function is expected to disappear within six to twelve months after treatment is stopped.

Ask your child's doctor about Triptodur.

Please see Important Safety Information for TRIPTODUR on pages 14-15.





## Trip started to notice other things too.



A changing body



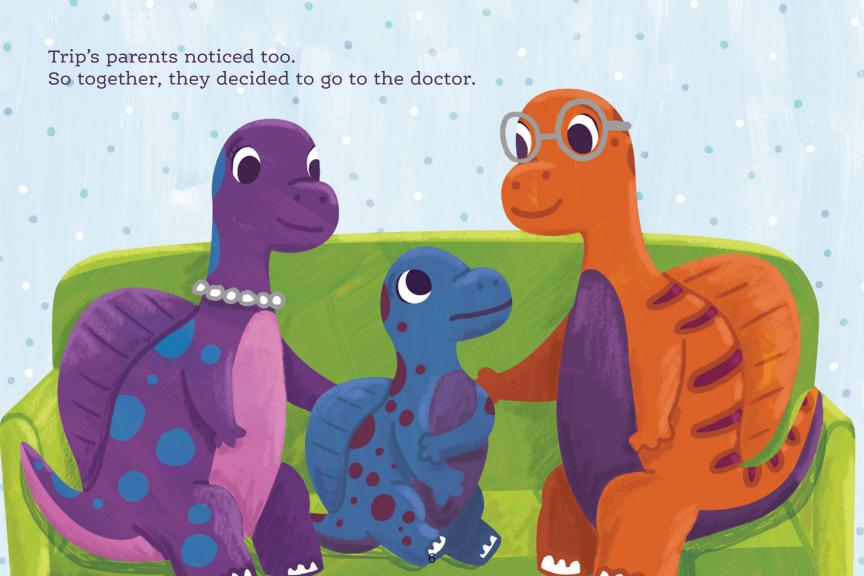
A changing voice



There were new smells



And new feelings



The doctor checked how Trip's body was growing:

An exam where the doctor touched and looked at Trip's body. Trip's parents let Trip know it was okay.



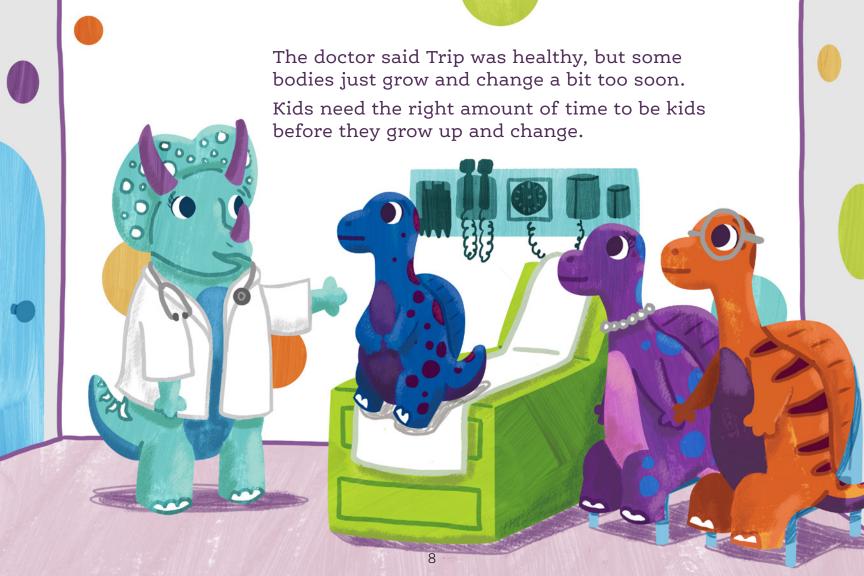


An X-ray that showed how Trip's bones were growing.

A test where they took blood to see how Trip's body is working inside.

The doctor asked Trip's parents some questions too.

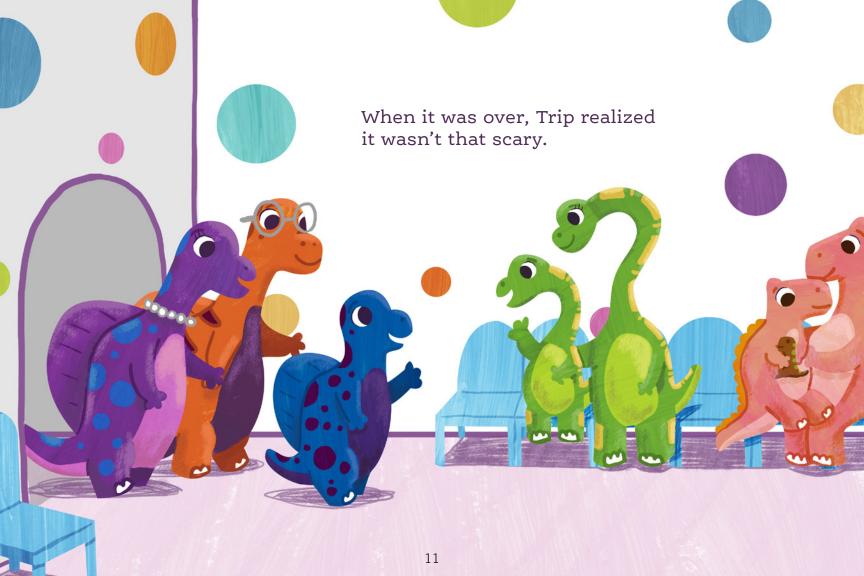








Trip knew the medicine was a shot and that shots may hurt, but the doctor and nurses were kind and helped Trip be brave.







#### IMPORTANT SAFETY INFORMATION FOR TRIPTODUR

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**

Do not use TRIPTODUR in:

- Those allergic to gonadotropin releasing hormone (GnRH), GnRH agonist medicines, or any ingredients in TRIPTODUR.
- children under 2 years of age
- women who are or may become pregnant

Tell your child's healthcare provider if any of the above conditions apply to your child.

It is important to stick to the dosing schedule (one injection every 24 weeks) in order for the drug to work. Do not miss or delay a scheduled dose.

Some people taking gonadotropin releasing hormone (GnRH) agonists like TRIPTODUR have had new

or worsened mental (psychiatric) problems. Mental (psychiatric) problems may include emotional symptoms such as crying, irritability, restlessness (impatience), anger, or acting aggressive. Call your child's doctor right away if your child has any new or worsening emotional symptoms while taking TRIPTODUR.

Some people taking GnRH agonists like TRIPTODUR have had seizures. The risk of seizures may be higher in people who have a history of seizures, have a history of epilepsy, have a history of brain or brain vessel (cerebrovascular) problems or tumors, are taking a medicine that has been connected with seizures such as bupropion or selective serotonin reuptake inhibitors (SSRIs). Seizures have also happened in people who have not had any of these problems. Call your child's doctor right away if your child has a seizure while taking TRIPTODUR.

Some people taking triptorelin, the active ingredient in TRIPTODUR, have had serious allergic reactions. Call your child's doctor or get emergency medical help right

#### **IMPORTANT SAFETY INFORMATION FOR TRIPTODUR** (continued)

away if your child gets any of the following symptoms of a serious allergic reaction: skin rashes, redness, or swelling, severe itching, hives, trouble breathing or swallowing, fast heartbeat, sweating, throat tightness, hoarseness, swelling of face, mouth, and tongue, dizziness or fainting.

The most common side effects of TRIPTODUR include 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). These are not all the possible side effects of TRIPTODUR. Tell your child's healthcare provider if they have any side effect that bothers them or that does not go away.

In the first few weeks after your child receives their first TRIPTODUR injection or after additional injections, TRIPTODUR can cause a brief increase in some hormones. During this time you may notice more signs of puberty in your child, including vaginal bleeding. Call your child's doctor if signs of puberty continue after 2 months of receiving TRIPTODUR.

Reports of pseudotumor cerebri (idiopathic intracranial hypertension) have been observed in pediatric patients receiving GnRH agonists, including triptorelin. Patients and caregivers should contact their healthcare provider if the patient develops any

of following symptoms of pseudotumor cerebri, including headache, and vision issues such as blurred vision, double vision, loss of vision, pain behind the eye or pain with eye movement, ringing in the ears, dizziness, and nausea.

These are not all the possible side effects of TRIPTODUR. Call your doctor for medical advice about side effects.

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.

### Trip was growing up fast.

But when Trip's parents began to notice Trip was so far ahead of friends, they decided to talk with a doctor.

Learn more







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