



**“A good day seems  
full of possibility”**

— Diana, mom of Lina

ZTALMY® could mean more days with fewer seizures for your child with CDKL5 deficiency disorder (CDD).

*Lina has CDD. She was not taking ZTALMY at the time of this photo.*

### **What is ZTALMY?**

- ZTALMY is a prescription medicine used to treat seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in people 2 years of age and older.
- ZTALMY is a federally controlled substance (CV) because it contains ganaxolone that can be abused and lead to dependence. Keep ZTALMY in a safe place to prevent misuse and abuse. Selling or giving away ZTALMY may harm others and is against the law. Tell your healthcare provider if you or your child have ever abused or been dependent on alcohol, prescription medicines or street drugs.
- It is not known if ZTALMY is safe and effective in children under 2 years of age.

Please see additional Important Safety Information throughout and click here for [Medication Guide](#).



**Ztalmy**®  
(ganaxolone) oral suspension | 50 mg/mL

## Seizures in CDD

# What would fewer seizures mean for your child with CDD?

Your family is likely familiar with how hard it is to control seizures associated with CDD. Your child may have tried several seizure medicines or may be on multiple medicines and still experiencing frequent seizures.

**Seizures can disrupt daily life.** They may cause your child to miss school, therapy, and other activities. Seizures can affect your family's balance of good days with CDD—the days with fewer seizures when you can interact more easily with your child or complete a therapy session.

Visit [ZTALMY.com/stories](https://www.ztalmymed.com/stories) to hear from families living with CDD

### Select Important Safety Information

**ZTALMY® (ganaxolone) CV can cause serious side effects, including:**

**Sleepiness:** ZTALMY may cause sleepiness. Taking ZTALMY with central nervous system (CNS) depressants including alcohol may increase sleepiness. **Do not** drive, operate heavy machinery, or do other dangerous activities until you know how ZTALMY affects you or your child.

Please see additional Important Safety Information throughout and click here for [Medication Guide](#).

“

*A bad day is always the same—holding Lina, rocking her, trying to soothe her.”*

— Diana, mom of Lina

*Lina has CDD. She was not taking ZTALMY at the time of this photo.*

## How ZTALMY may help your child with CDD

↓ **31%**  
SEIZURE  
REDUCTION  
with ZTALMY

vs

↓ **7%**  
SEIZURE  
REDUCTION  
with PLACEBO

### Proven effective in people with CDD

In the clinical study, ZTALMY significantly reduced the monthly seizure frequency over the 17-week treatment period. About half of participants (49) took ZTALMY and about half (51) received placebo. Those taking ZTALMY experienced a **4X reduction in median seizure frequency (31%), compared with placebo (7%).**

**1 in 4** experienced  
at least a **50%**  
seizure reduction

### Reduced the frequency of seizures by at least half for some study participants

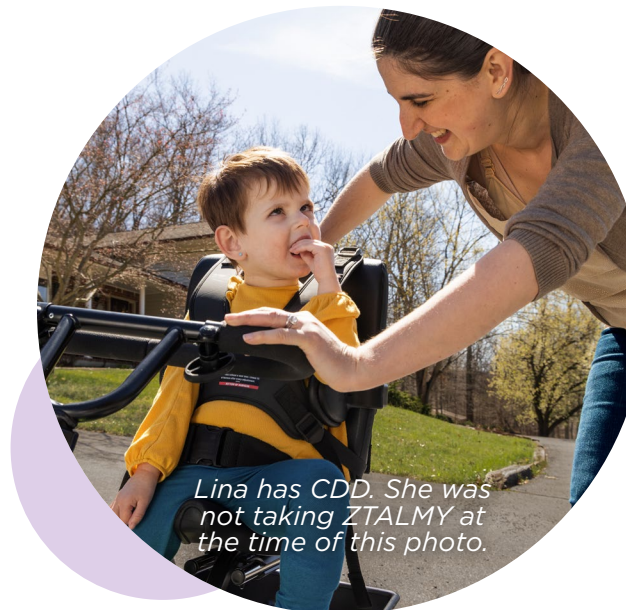
One in 4 participants taking ZTALMY had at least a 50% reduction in frequency of seizures vs 1 in 10 participants taking placebo.

Individual results may vary.

### Select Important Safety Information

**Suicidal Thoughts or Actions:** Like all other antiepileptic drugs, ZTALMY may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. **Call your healthcare provider right away if you or your child have any of these symptoms, especially if they are new, worse, or worry you:**

Please see additional Important Safety Information throughout and click here for [Medication Guide](#).



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### Studied in people with treatment-resistant seizures associated with CDD

- 101 children and young adults with CDD aged 2 to 19 years participated in the clinical study
- Participants had previously tried and discontinued between 1 and 16 seizure medicines
- Participants were taking on average 2 to 3 seizure medicines and were still having frequent seizures
- Seizure types that were assessed included bilateral tonic, generalized tonic-clonic, bilateral clonic, atonic, and focal to bilateral tonic-clonic

The first and only treatment indicated specifically for seizures associated with CDD in people 2 years of age and older

### Select Important Safety Information

- thoughts about suicide or dying
- attempt to commit suicide
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

**Ztalmy**®  
(ganaxolone) oral suspension | 50 mg/mL

## Side effects of ZTALMY

- In the clinical study, the most common side effects for ZTALMY (those that occurred in  $\geq 5\%$  of participants and twice the rate of placebo) included\*:
  - Sleepiness
  - Fever
  - Excessive salivation or drooling
  - Seasonal allergy
- 4% of participants taking ZTALMY discontinued treatment due to side effects vs 8% of participants taking placebo
  - Reasons for discontinuing ZTALMY were sleepiness and seizure (for 1 participant) and seizure (for 1 participant)

\*These are not all of the possible side effects of ZTALMY. Talk to your healthcare provider for medical advice about side effects.

Please see additional Important Safety Information throughout and click here for [Medication Guide](#).

In the clinical study, ZTALMY was used in combination with other seizure medicines

**98%** of participants taking ZTALMY were also taking other seizure medicines

Most common seizure medicines taken with ZTALMY: valproate, levetiracetam, clobazam, and vigabatrin.

Questions about ZTALMY? Visit [ZTALMY.com/resources](https://www.ztalmly.com/resources) to see FAQs

### Select Important Safety Information

**Pay attention to changes, especially sudden changes in mood, behaviors, thoughts, or feelings. Keep all follow-up visits with your healthcare provider as scheduled.**

**Stopping ZTALMY:** Do not stop taking ZTALMY without first talking to your healthcare provider. Stopping ZTALMY suddenly can cause you or your child to have seizures more often or seizures that do not stop (status epilepticus).

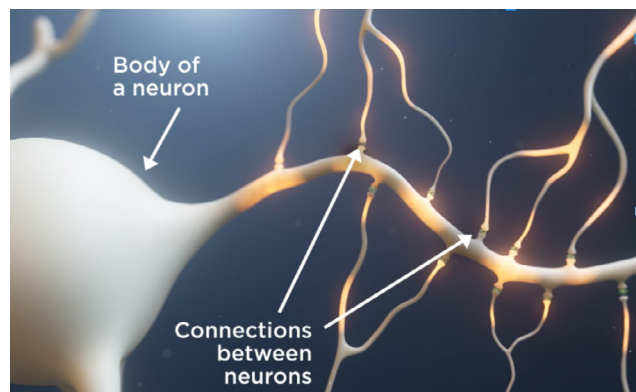


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**Ztalmly**®   
(ganaxolone) oral suspension | 50 mg/mL

## How ZTALMY works

ZTALMY is the first seizure medicine that is a neuroactive steroid. Exactly how ZTALMY works to treat seizures in CDD is not fully understood, but it is thought to reduce seizures by enhancing the activity of GABA (an inhibitory neurotransmitter) in the brain.



### The role of GABA

- The exact cause of seizures in CDD, like in other epilepsies, is not fully known. Seizures may result from an imbalance of excitatory (stimulating) and inhibitory (calming) signals in the brain.
- GABA, the main inhibitory neurotransmitter, plays an important role in sending inhibitory signals to calm excited neurons (nerve cells). When these signals do not work as they should, neurons may become overexcited, which can lead to seizures.

### Select Important Safety Information

**Before taking ZTALMY, tell your healthcare provider about all of your or your child's medical conditions, including if you or your child:**

- are pregnant or plan to become pregnant. Tell your healthcare provider right away if you or your child become pregnant while taking ZTALMY. You and your healthcare provider will decide if you or your child should take ZTALMY while pregnant.
- are breastfeeding or plan to breastfeed. ZTALMY may pass into breast milk. Talk to your healthcare provider about the best way to feed your or your child's baby while taking ZTALMY.

Please see additional Important Safety Information throughout and click here for [Medication Guide](#).



### The ZTALMY difference

- GABA sends inhibitory signals by attaching to certain GABA receptors found on neurons. Depending on their location, some of these receptors produce short bursts of inhibition, while others produce steady currents of inhibition.
- ZTALMY is a different kind of seizure medicine that enhances both types of inhibition by working on certain GABA receptors in different locations on the neuron. This dual approach may help to calm overexcited neurons.

### Select Important Safety Information

**Tell your healthcare provider about all the medicines you or your child take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. ZTALMY may affect the way other medicines work, and other medicines may affect how ZTALMY works. Do not stop or start taking other medicines without talking to your healthcare provider.



## What to know about taking ZTALMY

How should your child take ZTALMY?



Exactly as prescribed

3<sub>X</sub>

3 times a day



With food

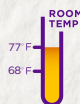
Before starting ZTALMY, read [How to Give ZTALMY](#) on ZTALMY.com.

Made with your child's needs in mind



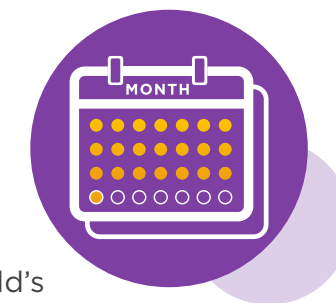
**Keto-friendly oral medicine.**

ZTALMY is a sugar-free, cherry-flavored liquid, suitable for ketogenic diets.



**Does not require refrigeration.**

Keep ZTALMY in a safe place to prevent misuse and abuse.



### ZTALMY dosing schedule

- For the first 3 weeks, your healthcare provider will likely increase your child's dose each week depending on how well your child is tolerating ZTALMY
- Give ZTALMY exactly as your healthcare provider tells you. Your healthcare provider will tell you how much ZTALMY to give and when to give it
- Use the bottle adaptor and oral dosing syringes provided by the specialty pharmacy to administer ZTALMY. Do not use a household teaspoon or tablespoon
- Your healthcare provider may adjust the dose of ZTALMY as your child's weight changes

Please see [Instructions for Use](#) for more information.

### Select Important Safety Information

**Especially tell your healthcare provider if you or your child take:** alcohol; opioids; antidepressants.

Please see additional Important Safety Information throughout and click here for [Medication Guide](#).

### Select Important Safety Information

Know the medicines you or your child take. Keep a list of them to show your healthcare provider or pharmacist when you or your child get a new medicine.

**Do not** drive, operate heavy machinery, or do other dangerous activities until you know how ZTALMY affects you or your child. ZTALMY may cause you or your child to feel sleepy.



## Support for your ZTALMY® journey



Ztalmy one™

ZTALMY One is a comprehensive support program for you and your child.

### ZTALMY One support includes:

- Benefits verification
- Prescription delivery
- ZTALMY cost support\*
- Ongoing prescription support



### ZTALMY One helps make treatment more *affordable*

Whether your family is insured, underinsured, or not insured at all, ZTALMY One has copay and prescription support programs that may help make treatment more affordable.

\*Enrollment in ZTALMY One is required.

Please see additional Important Safety Information throughout and click here for [Medication Guide](#).

## Talking to your child's healthcare provider

Talk to your healthcare provider about the opportunity to reduce your child's seizures and what more "good days" could mean for your family. These questions can help you start a conversation about whether it is time to consider ZTALMY.



### About seizure management in CDD

- Which seizure medicines have been studied for CDD?
- Are my child's seizure medicines effective at reducing the frequency of seizures associated with CDD?
- What is the goal of our seizure management plan?

### About ZTALMY

- Can ZTALMY help us reach our seizure management goals?
- Will ZTALMY work with my child's current treatment plan?
- What are the potential risks and benefits of ZTALMY?

Bring these questions to your next appointment



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## INDICATION

### What is ZTALMY?

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- ZTALMY is a federally controlled substance (CV) because it contains ganaxolone that can be abused and lead to dependence. Keep ZTALMY in a safe place to prevent misuse and abuse. Selling or giving away ZTALMY may harm others and is against the law. Tell your healthcare provider if you or your child have ever abused or been dependent on alcohol, prescription medicines or street drugs.
- It is not known if ZTALMY is safe and effective in children under 2 years of age.

### IMPORTANT SAFETY INFORMATION

#### What is the most important information I should know about ZTALMY?

##### ZTALMY can cause serious side effects, including:

**Sleepiness:** ZTALMY may cause sleepiness. Taking ZTALMY with central nervous system (CNS) depressants including alcohol may increase sleepiness. **Do not** drive, operate heavy machinery, or do other dangerous activities until you know how ZTALMY affects you or your child.

**Suicidal Thoughts or Actions:** Like all other antiepileptic drugs, ZTALMY may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.

#### Call your healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempt to commit suicide
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

#### Pay attention to changes, especially sudden changes in mood, behaviors, thoughts, or feelings. Keep all follow-up visits with your healthcare provider as scheduled.

**Stopping ZTALMY:** Do not stop taking ZTALMY without first talking to your healthcare provider. Stopping ZTALMY suddenly can cause you or your child to have seizures more often or seizures that do not stop (status epilepticus).

#### What should I tell my healthcare provider?

##### Before taking ZTALMY, tell your healthcare provider about all of your or your child's medical conditions, including if you or your child:

- drink alcohol.
- have or have had depression, mood problems or suicidal thoughts or behavior.

- have abused or been dependent on prescription medicines, street drugs, or alcohol.
- have liver problems.
- are pregnant or plan to become pregnant. Tell your healthcare provider right away if you or your child become pregnant while taking ZTALMY. You and your healthcare provider will decide if you or your child should take ZTALMY while pregnant.
- are breastfeeding or plan to breastfeed. ZTALMY may pass into breast milk. Talk to your healthcare provider about the best way to feed your or your child's baby while taking ZTALMY.

**Tell your healthcare provider about all the medicines you or your child take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. ZTALMY may affect the way other medicines work, and other medicines may affect how ZTALMY works. Do not stop or start taking other medicines without talking to your healthcare provider.

**Especially tell your healthcare provider if you or your child take:** alcohol; opioids; antidepressants.

Know the medicines you or your child take. Keep a list of them to show your healthcare provider or pharmacist when you or your child get a new medicine.

#### What should be avoided while taking ZTALMY?

**Do not** drive, operate heavy machinery, or do other dangerous activities until you know how ZTALMY affects you or your child. ZTALMY may cause you or your child to feel sleepy.

#### What are the side effects of ZTALMY?

##### See "What is the most important information I should know about ZTALMY?"

##### The most common side effects of ZTALMY include:

- sleepiness
- fever
- excessive saliva or drooling
- seasonal allergy

These are not all of the possible side effects of ZTALMY. For more information ask your healthcare provider or pharmacist. Tell your healthcare provider about any side effect that bothers you or your child or that does not go away.

##### Call your doctor for medical advice about side effects.

You may report side effects to the FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

You may also contact Marinus Pharmaceuticals directly at 844-627-4687.

For additional information, please click here for [Medication Guide and Instructions for Use](#) and discuss with your doctor.








“  
*When it's a good day,  
we can go outside or  
we can play or we can do  
some therapies together.”*

*— Diana, mom of Lina*

**Ask your healthcare provider  
about ZTALMY and if it is right  
for your child.**

**Visit [ZTALMY.com](https://ZTALMY.com) for resources  
and additional information**

A photograph of a woman with dark hair tied back, wearing a brown cardigan and blue jeans, smiling as she assists a young child on a green tricycle. The child is wearing a yellow shirt and blue pants. They are outdoors on a paved path with trees in the background.

*Lina has CDD. She was not taking  
ZTALMY at the time of this photo.*

Please see additional Important Safety Information throughout and click here for [Medication Guide](#).

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