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



Lina is living with CDD.

What would fewer seizures mean for your loved one living with CDKL5 deficiency disorder (CDD)?

A guide to talking with your healthcare provider about ZTALMY and seizures associated with CDD

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 **Important Safety Information** on pages 4-5 of this guide and click here for **Medication Guide**.

Start a conversation about the possibility of taking ZTALMY® for seizures associated with CDD

Seizures can affect your family's balance of good days with CDD—the days with fewer seizures when you can connect more easily with your loved one or that he or she can complete a therapy session.

Talk to your healthcare provider about the possibility of reducing the frequency of your loved one's seizures with ZTALMY. This guide can help you start a conversation about your loved one's seizure activity, what more good days could mean for your loved one, and whether it is time to consider ZTALMY.

Information to share at your next appointment

Tip: Fill in your responses ahead of the appointment. The more information you share, the more your healthcare provider will understand how seizures associated with CDD affect your loved one and his or her ability to have a good day.

How many good days (days with fewer seizures) does your loved one have per month?

Good days _____

Do the seizures affect your loved one's daily routine or his or her ability to participate in therapy, school, and/or activities with your family?

- ☐ *Rarely*
- ☐ *Sometimes*
- ☐ *Most days*
- ☐ *Every day*

What is your level of satisfaction with your loved one's current seizure medicine(s)?

(Not satisfied) *(Satisfied)*

☐—☐—☐—☐—☐

1 *2* *3* *4* *5*

☐ *Currently, my loved one is not taking any seizure medicines*

Over the last 1 to 3 months, have your loved one's seizures gotten worse, improved, or stayed the same?

- ☐ *Worse*
- ☐ *Improved*
- ☐ *Stayed the same*

Over the last 1 to 3 months, how often has your loved one had seizures?

- ☐ *Multiple times a day*
- ☐ *About once a day*
- ☐ *A few times per week*
- ☐ *Other*

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Questions to ask your doctor about seizures associated with CDD

- Which seizure medicines have been studied specifically in CDD?
- Are my loved one's seizure medicine(s) effective at reducing the frequency of seizures associated with CDD?
- What is the goal of our seizure management plan?

Questions to ask your doctor about ZTALMY®

- Can ZTALMY help us reach our seizure management goals?
- Will ZTALMY work with my loved one's current treatment plan?
- What are the potential risks and benefits of ZTALMY?
- How is ZTALMY different from other medicines used to treat seizures in CDD?
- How do you take ZTALMY, and how often do you take the medicine?
- Is ZTALMY flavored?
- Can ZTALMY be used with a ketogenic diet?
- Can my loved one take a medicine like ZTALMY with a feeding tube?

Notes: _____

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- 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 or your child 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 or 1-800-FDA-1088.** You may also contact Immedica at **1-844-627-4687.**

Please see Full Prescribing Information and Medication Guide or visit www.ztalmy.com for more information.

Immedica pharma

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