

Getting Started With **ZTALMY**

Gigi is living 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 additional Important Safety Information throughout and click here for [Medication Guide](#).

Welcome to Ztalmy^{one}TM

We are here to *support* you

Starting a new seizure medicine may be challenging, but know that you are not alone. ZTALMY One, a comprehensive support program, is here to help you and your loved one throughout your ZTALMY[®] treatment journey. This booklet can help you learn more about starting ZTALMY and the support services we offer.

Reach out to ZTALMY One

Our dedicated support team includes Patient Care Coordinators* (available Monday through Friday, 8 AM to 8 PM ET) and pharmacists, available 24/7, to answer questions you may have.

Call **1-844-ZTALMY-1** (1-844-982-5691). Scan the QR code to the right to save our number to your phone.



*Eligibility Terms and Conditions apply. ZTALMY One Patient Care Coordinators do not provide medical advice or individual patient care. For medical questions, be sure to consult your healthcare provider.

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.

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

About your loved one's new treatment

ZTALMY is the first treatment indicated specifically for seizures associated with CDKL5 deficiency disorder (CDD) in people 2 years and older.



Studied in children and young adults with CDD

The clinical study included 101 participants aged 2 to 19 years. Participants had treatment-resistant seizures associated with CDD.



Proven to reduce the frequency of seizures in CDD

In the clinical study, ZTALMY significantly reduced the frequency of monthly seizures vs placebo over 17 weeks. **Individual results may vary.**

Inside this booklet you will find:

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Support throughout your treatment journey



ZTALMY One is a comprehensive support program for you and your loved one. ZTALMY One helps with access and affordability, and provides ongoing prescription support and education, so you can focus on being there for your loved one.



Facilitating *access* to treatment

After your doctor prescribes ZTALMY®, a Patient Care Coordinator will contact you within 1 or 2 business days. The Patient Care Coordinator will let you know that ZTALMY One is working with your doctor and your insurance provider to verify your benefits and help navigate your insurance coverage. This process may take some time, but a Patient Care Coordinator will provide weekly updates on the progress of confirming your coverage.



Delivering your *prescription*

Once your insurance coverage is confirmed, you will receive a call from a Patient Care Coordinator, who will schedule your prescription delivery and discuss any out-of-pocket costs.

Important: Please answer and return calls from **ZTALMY One (1-844-982-5691)** to ensure that you receive your child's prescription as soon as possible.

Sign the enrollment form provided by your doctor so you can receive additional resources and educational information in the future



Providing prescription *support*

ZTALMY One has prescription support programs that can help make your ZTALMY prescription more affordable.

- **ZTALMY One Copay Savings Program**

Through the ZTALMY One Copay Savings Program, commercially insured eligible patients may pay as low as zero dollars per fill for a ZTALMY prescription*

- **ZTALMY One Prescription Support Programs**

If your loved one has no insurance, limited insurance, or a gap or delay in coverage, ZTALMY One Prescription Support Programs may be able to help with the cost of treatment with ZTALMY.

*Eligible patients may pay as low as \$0 per fill for ZTALMY prescription for a maximum 30-day supply per fill, subject to an annual maximum. State and federal health care program beneficiaries not eligible even if they elect to be processed as an uninsured (cash-paying) patient. The savings program is not health insurance. Immedica Pharma US Inc. reserves the right to rescind, revoke or amend this offer without notice. See full terms and conditions. For questions, please call ZTALMY One (1-844-982-5691).

Program Eligibility and Terms and Conditions

The copay savings program requires a valid prescription for ZTALMY (ganaxolone) oral suspension, CV consistent with the Prescribing Information. Patient must have commercial insurance. Offer is not valid for cash-paying patients. Patient must reside in the U.S. or U.S. Territory. Patients are responsible for as low as a zero-dollar copayment for a ZTALMY prescription for a maximum 30-day supply per fill. The value of the copay savings program offer is limited to an annual maximum per calendar year. For maximum annual benefit limit information, please contact ZTALMY One (1-844-982-5691). Patients are not eligible to use this offer if they are eligible for or enrolled in a state or federally funded insurance program, including but not limited to Medicare, Medicaid, TRICARE, Veteran Affairs health care or a state prescription drug assistance program. Patients are responsible for reporting use of the copay savings program to any commercial insurer, health plan, or other third party who pays for or reimburses any part of the prescription filled using the copay savings program, as may be required. Patients should not use the copay savings program if their insurer or health plan prohibits use of manufacturer copay programs. Offer not valid where prohibited by law. Copay Savings Program accepted only by the ZTALMY One designated specialty pharmacy. If patient's insurance changes, the pharmacy must be notified immediately. Based on patient's insurance change, patient may no longer be able to participate in the copay savings program. Offer is not health insurance. Offer good only in the U.S. Offer is limited to one per person during this offering period and is not transferable. Offer is not conditioned on any past, present, or future purchase, including refills. Immedica Pharma US Inc. reserves the right to rescind, revoke or amend this offer and program eligibility requirements at any time without notice.



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

Dosing information

How should your loved one take ZTALMY®?



Exactly as prescribed

3x

3 times a day



With food

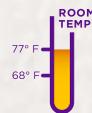
Before starting ZTALMY, read [How to Give ZTALMY](#) on page 8.

Made with your loved one's needs in mind



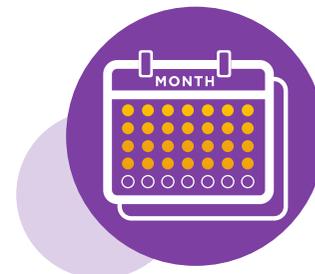
Keto-friendly oral medicine.

ZTALMY is a sugar-free, cherry-flavored liquid that is 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 28 days, your healthcare provider will likely increase your loved one's dose each week depending on how well your loved one 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 your pharmacist to administer ZTALMY. Do not use a household teaspoon or tablespoon
- Your doctor may adjust the dose of ZTALMY as your loved one's weight changes

Use the [treatment tracker](#) to record your loved one's dose. Your healthcare provider will tell you how much to give and when to give ZTALMY.

Important Safety Information

What should I tell my health care provider?

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.

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

Important Safety Information (continued)

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.

Ztalmy [®] _©
(ganaxolone) oral suspension | 50 mg/mL

How to Give ZTALMY®

Each package contains:



Bottle(s) of ZTALMY with a child-resistant cap

Other supplies provided:

- press-in bottle adaptor
- oral syringe(s)

Your pharmacist will provide you with a press-in bottle adaptor and the right sized oral syringe(s) based on the prescribed dose.

If you do not have a press-in bottle adaptor and the right sized oral syringe(s) to use with your medicine, call your pharmacist right away (available 24/7) through the **ZTALMY One™ patient support program: 1-844-ZTALMY-1 (1-844-982-5691)**.

Note: If you lose or damage an oral syringe, or cannot read the markings, contact your pharmacist for a new oral syringe.

Follow these instructions to use the press-in bottle adaptor and oral syringe to measure and give ZTALMY.

Be sure that you read, understand, and follow these instructions carefully to ensure proper dosing of the oral suspension.

Important:

- Follow your healthcare provider's instructions for how to give ZTALMY.
- ZTALMY should always be given with food.
- Ask your healthcare provider or pharmacist if you are not sure how to prepare or give the prescribed dose of ZTALMY.
- Always use the oral syringe(s) provided by your pharmacist to make sure you measure the right amount of ZTALMY. A household teaspoon or tablespoon is not an adequate measuring device and should not be used.
- Do not give ZTALMY after the expiration date on the package and each bottle.
- Use ZTALMY within 30 days of first opening the bottle.
- After 30 days of first opening the bottle, safely throw away (dispose of) any ZTALMY that has not been used.

Prepare the bottle

Shake well



1

Hold the bottle in your hand and shake it up and down well for 1 minute.

Always shake the bottle well for 1 minute then let the bottle stand for 1 minute so that any foam buildup during shaking can settle before measuring and giving **each dose** of ZTALMY. This helps you measure the correct amount of medicine.

Note: This step is for each dose of the medicine.



2

Remove the child-resistant cap by pushing down while turning the cap to the left (counter-clockwise).



3

Puncture and peel off the induction seal from the bottle.

Note: This step is only for the first use of the bottle.



4

Push the press-in bottle adaptor firmly into the bottle. Firmly grasp the bottle in one hand and insert the press-in bottle adaptor all the way in the bottle with the other hand using constant pressure. Make sure the press-in bottle adaptor is fully inserted. If not fully inserted, small parts such as the press-in bottle adaptor may become a choking hazard for children and pets.

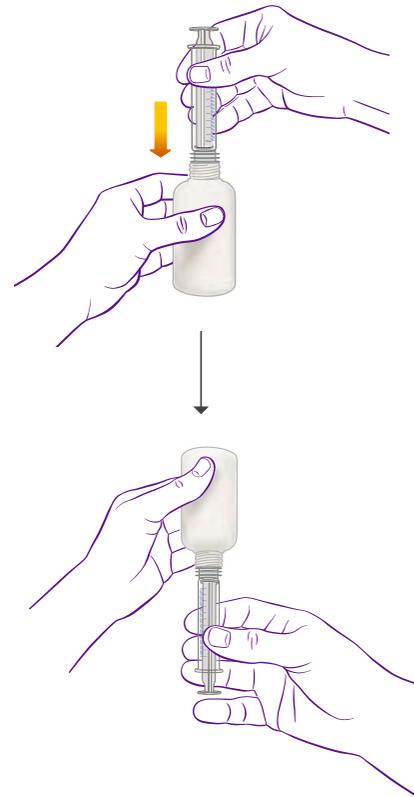
Note: Do not remove the press-in bottle adaptor from the bottle after it is inserted.

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

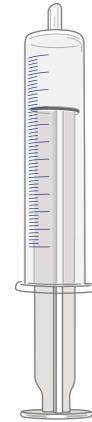
How to Give ZTALMY® (continued)

Prepare the dose

Your healthcare provider will tell you how much ZTALMY to give.



5 Gather the oral syringe, push the plunger all the way down, then insert the tip of the oral syringe fully into the press-in bottle adaptor. With the oral syringe in place, turn the bottle upside down.

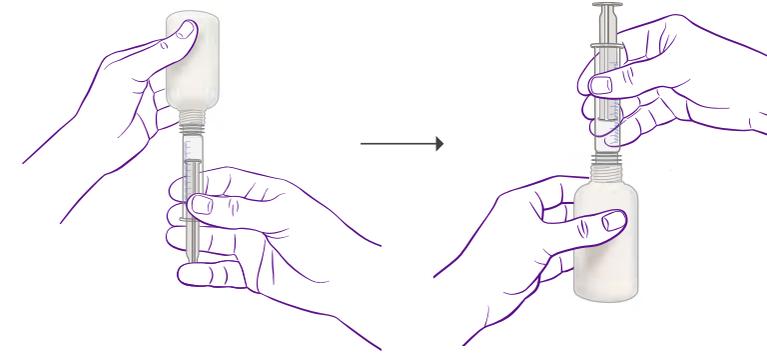


6 Slowly pull the plunger of the oral syringe to withdraw the dose of ZTALMY needed. Line up the end of the plunger with the marking for your dose of ZTALMY.

Note: Your syringe(s) may look different from the one pictured, depending on the dose prescribed.

! **What to do if you see air bubbles:**
If there are air bubbles in the oral syringe, keep the bottle upside down and slowly push the plunger so that all of the liquid flows back into the bottle. Repeat Step 6 until air bubbles are gone.

7 When you have measured the correct amount of ZTALMY, leave the oral syringe in the press-in bottle adaptor and turn the bottle right side up.



8 Carefully remove the oral syringe from the press-in bottle adaptor.



Give ZTALMY

9 Place the tip of the oral syringe against the inside of the cheek and gently push the plunger until all of the ZTALMY in the oral syringe is given.



Do not forcefully push the plunger.

Do not direct the medicine to the back of the mouth or throat. This may cause choking.

10 Screw the child-resistant cap back on the bottle tightly by turning the cap to the right (clockwise). Do not remove the press-in bottle adaptor. The child-resistant cap will fit over it.



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

Frequently asked questions about ZTALMY®

Q: How much will ZTALMY cost?

A: ZTALMY One™ Patient Care Coordinators can help determine how much your loved one's ZTALMY will cost you. ZTALMY One also provides prescription support programs to help make treatment more affordable. See page 5 to learn more.

Q: Is ZTALMY covered by insurance?

A: ZTALMY One Patient Care Coordinators will work with your doctor and your insurance provider to verify your benefits. ZTALMY One also offers prescription support programs for eligible patients to help make treatment more affordable. If you have questions about whether your insurance covers ZTALMY, call ZTALMY One at 1-844-ZTALMY-1 (1-844-982-5691).

Q: Can I give ZTALMY with other medicines?

A: In the clinical trial, 98% of participants taking ZTALMY were also taking other seizure medicines. The most common seizure medicines that were taken were valproate, levetiracetam, clobazam, and vigabatrin. 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.

Q: How should I store ZTALMY?

A: Store ZTALMY at 68°F to 77°F. Always store ZTALMY in its original bottle in an upright position. Keep the child-resistant cap tightly closed. Use ZTALMY within 30 days of first opening the bottle. Throw away (dispose of) any unused medicine after 30 days. Keep ZTALMY and all medicines out of the reach of children.

Q: Is there artificial sweetener in ZTALMY?

A: Yes, ZTALMY includes artificial cherry flavoring and sucralose. The liquid formulation is sugar-free and suitable for ketogenic diets.

Q: Can ZTALMY be given through my loved one's feeding tube?

A: Ask your healthcare provider about giving ZTALMY through a feeding tube.

Important Safety Information

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
- excessive saliva or drooling
- fever
- seasonal allergy



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.

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 Prescription Information** and **Medication Guide** or visit www.ztalmly.com for more information.





Support throughout your treatment journey

As your loved one starts treatment, ZTALMY One* will support you every step of the way. ZTALMY One will call you every month to

- Check for any weight changes that could affect your loved one's dose
- Provide refill reminders
- Schedule your next delivery of ZTALMY®

*Eligibility Terms and Conditions apply.

Remember, you can always reach out to ZTALMY One (1-844-982-5691). Scan the QR code to save our number directly to your phone.



Visit ZTALMY.com/stayinformed for additional information about ZTALMY

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



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PRC-US-Zta-00110-v2 2/26

