

MEDICATION GUIDE
ZTALMY™ (zuh tal' mee)
(ganaxolone)
oral suspension, CV

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

ZTALMY can cause serious side effects, including:

1. 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. Like other antiepileptic drugs, ZTALMY may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.

Call a 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

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings.
 - Keep all follow-up visits with your healthcare provider as scheduled.
3. Do not stop taking ZTALMY without first talking to your healthcare provider. Stopping a seizure medicine such as ZTALMY suddenly can cause you or your child to have seizures more often or seizures that do not stop (status epilepticus).

Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

WHAT IS ZTALMY?

- ZTALMY is a prescription medicine that is 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.

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.
 - if you or your child become pregnant while taking ZTALMY, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry. You can enroll in this registry by calling 1-888-233-2334 or go to <http://www.aedpregnancyregistry.org/>. The purpose of this registry is to collect information about the safety of antiepileptic drugs during pregnancy.
- 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.

How should I take ZTALMY?

- Read the **Instructions for Use** at the end of this Medication Guide for information on the right way to use ZTALMY.
- Take or give ZTALMY exactly as your healthcare provider tells you.
- Your healthcare provider will tell you how much ZTALMY to take or give and when to take or give it.
- Measure each dose of ZTALMY using the bottle adapter and oral dosing syringes provided by your pharmacist. Do not use a household teaspoon or tablespoon. If your dose of ZTALMY is less than 1 mL, your pharmacist will provide you with an appropriately sized syringe to take or give ZTALMY.
- Take or give ZTALMY with food.
- In case of overdose, get medical help or contact a live Poison Center expert right away.

What should I avoid 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 possible side effects of ZTALMY?

ZTALMY can cause serious side effects, including:

- 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 FDA at 1-800-FDA-1088.

You may also contact Immedica Pharma US at 1-844-627-4687.

How should I store ZTALMY?

- Store ZTALMY at 68°F to 77°F (20°C to 25°C).
- 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.

General Information about the safe and effective use of ZTALMY.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ZTALMY for a condition for which it was not prescribed. Do not give ZTALMY to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about ZTALMY that is written for health professionals.

What are the ingredients in ZTALMY?

Active ingredient: ganaxolone

Inactive ingredients: artificial cherry flavor, citric acid, hypromellose, methylparaben, polyvinyl alcohol, propylparaben, purified water, simethicone emulsion, sodium benzoate, sodium citrate, sodium lauryl sulfate and sucralose.

Manufactured for Immedica Pharma AB, Stockholm, Sweden

Marketed by Immedica Pharma US Inc., Chicago, IL 60642

For more information, go to www.ZTALMY.com or call 844-IMMEDICA (1-844-627-4687).

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This Medication Guide has been approved by the U.S. Food and Drug Administration

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INSTRUCTIONS FOR USE
ZTALMY® (zuh-tal' mee)
(ganaxolone)
oral suspension, CV
50 mg/mL

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 take or give ZTALMY.
- ZTALMY should always be given with food.
- Ask your healthcare provider or pharmacist if you are not sure how to prepare, take, or give the prescribed dose of ZTALMY.
- Always use the oral syringe provided by your pharmacist to make sure you measure the right amount of ZTALMY.
- Do not use 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.

Each package contains:

1 bottle of ZTALMY with a child resistant cap:



Supplies **not included** in the package:

- press-in bottle adapter
- oral syringe

You can get a press-in bottle adapter and oral syringes from your pharmacy. Your pharmacist can help you choose the right press-in bottle adapter and oral syringe to use with ZTALMY.

Call your pharmacist right away if you do not have a press-in bottle adapter and the right sized oral syringe to use with your medicine.

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

Follow the instructions below to use the press-in bottle adapter and oral syringe to measure and take or give ZTALMY.

Prepare the bottle

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 build up 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.

SHAKE WELL

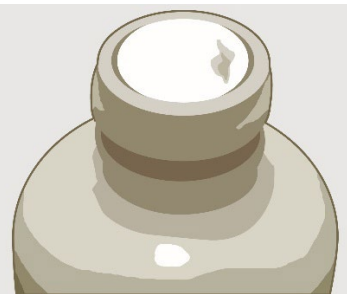


2. Remove the child-resistant cap by pushing down while turning the cap to the left (counter-clockwise).



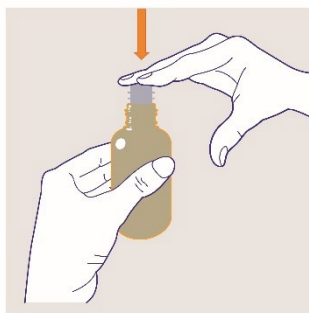
3. Puncture and peel off the induction seal from the bottle.

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



4. Push the press-in-bottle adapter firmly into the bottle. Firmly grasp the bottle in one hand and insert the press-in bottle adapter 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 adapter from the bottle after it is inserted.



Prepare the dose

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

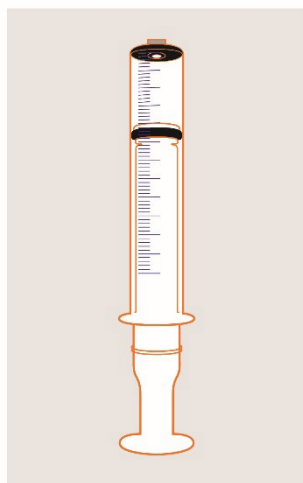
5. Gather the oral syringe, push the plunger all the way down then insert the tip of the oral syringe fully into the press-in bottle adapter. With the oral syringe in place, turn the bottle upside down.

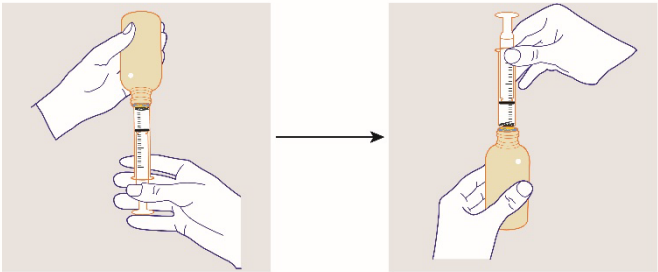


6. Slowly pull the plunger of the oral syringe to withdraw the dose of ZTALMY needed. Line up the end of the plunger with the marking for your dose of ZTALMY.

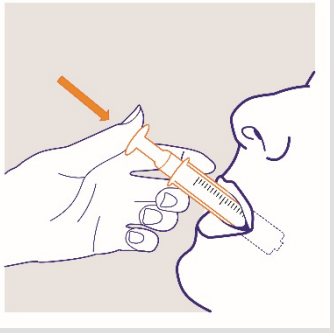
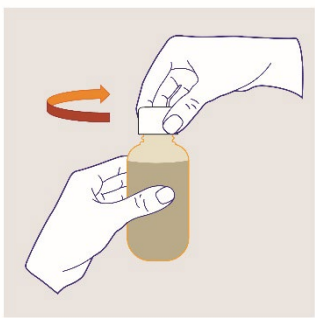
What to do if you see air bubbles:

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 adapter and turn the bottle right side up.	
8. Carefully remove the oral syringe from the press-in bottle adapter.	

Take or 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 taken or 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 adapter. The child-resistant cap will fit over it.	

How should I store ZTALMY?

- Store ZTALMY at 68°F to 77°F (20°C to 25°C).
- Always store ZTALMY in its original bottle in an upright position.
- Keep the child-resistant cap tightly closed.
- Use 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.

Helpline Details

For additional assistance, call the toll-free helpline at 844-IMMEDICA (1-844-627-4687). Hours: Monday - Friday 8:00 am to 6:00 pm EST

Frequently asked Questions:

Q: What if there are air bubbles in the oral syringe?

A: Slowly push the liquid back into the bottle and repeat step 6 until the air bubbles are gone.

Manufactured for Immedica Pharma AB, Stockholm, Sweden

Marketed by Immedica Pharma US Inc., Chicago, IL 60642

For more information, go to www.ZTALMY.com or call 1-484-801-4670.

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