Dosing and Titration Reference for ZTALMY®

ZTALMY (ganaxolone) oral suspension CV is indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years of age and older.

Oral dosing and gradual titration for patients with CDD

- ZTALMY is a liquid formulation administered by mouth using an oral syringe **3 times daily** and must be **taken with food**
- Each mL of ZTALMY oral suspension contains 50 mg of ganaxolone
- Recommended standard maintenance dosage is **63 mg/kg/day divided into 3 doses**, up to a maximum of **1,800 mg/day**
- Dose adjustments may be required if your patient's weight changes; check your patient's weight regularly
- For patients with severe hepatic impairment, dosage adjustments are required during titration and maintenance

Recommended Titration Schedule

Days	Standard Dosage		Severe Hepatic Impairment*	
	Patients ≤28 kg	Patients >28 kg	Patients ≤28 kg	Patients >28 kg
Titration Week 1 Days 1-7	2 mg/kg three times daily (6 mg/kg/day)	50 mg three times daily (150 mg)	0.66 mg/kg three times daily (2 mg/kg/day)	17 mg three times daily (50 mg)
Titration Week 2 Days 8-14	4 mg/kg three times daily (12 mg/kg/day)	100 mg three times daily (300 mg)	1.33 mg/kg three times daily (4 mg/kg/day)	33 mg three times daily (100 mg)
Titration Week 3 Days 15-21	8 mg/kg three times daily (24 mg/kg/day)	200 mg three times daily (600 mg)	2.66 mg/kg three times daily (8 mg/kg/day)	67 mg three times daily (200 mg)
Titration Week 4 Day 22-28	14 mg/kg three times daily (42 mg/kg/day)	400 mg three times daily (1,200 mg)	4.66 mg/kg three times daily (14 mg/kg/day)	133 mg three times daily (400 mg)
Maintenance Day 29 and thereafter	21 mg/kg three times daily (63 mg/kg/day)	600 mg three times daily (1,800 mg)	7 mg/kg three times daily (21 mg/kg/day)	200 mg three times daily (600 mg)

*Dosage adjustments are required for patients with severe hepatic impairment (Child-Pugh class C). No dosage adjustments are necessary in patients with mild (Child-Pugh class A) or moderate (Child-Pugh class B) hepatic impairment. Total daily dose is an approximation.

Titration information: Dosage should be increased based on tolerability no more frequently than every 7 days. Titration increments should not exceed those shown in the chart above.

Dose adjustments: In the pivotal trial, 22% of patients taking ZTALMY had a dose interruption or reduction due to an adverse reaction—most frequently somnolence (10%) and sedation (2%)—compared with 16% of patients taking placebo.

Drug interactions: Cytochrome P450 inducers will decrease ganaxolone exposure. Avoid concomitant use with strong or moderate CYP3A4 inducers; if unavoidable, consider a dosage increase of ZTALMY, but do not exceed the maximum recommended dosage. UGT inhibitors may increase ganaxolone exposure. Consider a reduction of ZTALMY maintenance dose when initiating UGT inhibitors.

Discontinuation: Decrease the dose of ZTALMY gradually when discontinuing treatment. As with all antiepileptic drugs, abrupt discontinuation should be avoided, when possible, to minimize the risk of increased seizure frequency and status epilepticus.

For standard dosage: Calculate your patient's dose in mg and mL
at **ztalmyhcp.com/calculator**

Please see **Important Safety Information** on back and consult the full **Prescribing Information**.

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

Starting your patients on ZTALMY®
ZTALMY is supplied through Orsini Specialty Pharmacy by ZTALMY One™, a comprehensive patient services program that facilitates access to treatment. For prescription support, call **1-844-ZTALMY-1** (Monday through Friday, 8 AM to 8 PM ET). For prescribing resources including the ZTALMY One enrollment form, visit **ztalmyhcp.com/prescribe**.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Somnolence and Sedation:** ZTALMY can cause somnolence and sedation. In a clinical study somnolence and sedation appeared early during treatment and were generally dose related. Other CNS depressants, including opioids, antidepressants, and alcohol, could potentiate these effects. Monitor patients for these effects and advise them not to drive or operate machinery until they have gained sufficient experience on ZTALMY to gauge whether it adversely affects their ability to drive or operate machinery.
- **Suicidal Behavior and Ideation:** Antiepileptic drugs (AEDs), including ZTALMY, increase the risk of suicidal thoughts or behavior. Monitor patients taking ZTALMY for the emergence or worsening of depression, suicidal thoughts or behavior, or any unusual changes in mood or behavior. Advise patients, caregivers, and their families to be alert for these behavioral changes and report behaviors of concern immediately to healthcare providers. When considering ZTALMY, or any other AED, balance the risk of suicidal thoughts or behaviors with the risk of untreated illness. If these symptoms emerge during treatment, consider whether it may be related to the AED or the underlying illness.
- **Withdrawal of Antiepileptic Drugs:** As with most AEDs, withdraw ZTALMY gradually to minimize the risk of increased seizure frequency and status epilepticus. If withdrawal is needed because of a serious adverse event, rapid discontinuation can be considered.

ADVERSE REACTIONS

The most common adverse reactions (incidence of at least 5% and at least twice the rate of placebo) were somnolence (38%), pyrexia (18%), salivary hypersecretion (6%), and seasonal allergy (6%).

DRUG INTERACTIONS

Cytochrome P450 inducers will decrease ganaxolone exposure. Avoid concomitant use with strong or moderate CYP3A4 inducers; if unavoidable, consider a dosage increase of ZTALMY, but do not exceed the maximum recommended dosage.

UGT inhibitors may increase ganaxolone exposure. Consider a reduction of ZTALMY maintenance dose when initiating UGT inhibitors.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Use caution when ZTALMY is administered to pregnant women as there are no adequate data on the developmental risk associated with use in pregnant women. In animal studies, developmental adverse effects were observed following exposure during organogenesis or throughout gestation and lactation.
- **Lactation:** ZTALMY is excreted in human milk at concentrations resulting in a dose to the breastfed infant of less than 1% maternal dose. The effects of ZTALMY on milk production and the breastfed infant are unknown.
- **Hepatic Impairment:** Administration of ZTALMY in patients with severe hepatic impairment (Child-Pugh class C) results in elevated ganaxolone plasma concentrations. Therefore, dosage adjustment in these patients during titration and maintenance is required. No dosage adjustment is necessary in patients with mild (Child-Pugh class A) or moderate (Child-Pugh class B) hepatic impairment.

DRUG ABUSE AND DEPENDENCE

ZTALMY contains ganaxolone, a Schedule V controlled substance (CV). Advise patients of the potential for abuse and dependence. It is recommended that ZTALMY be tapered according to the dosage recommendations unless symptoms warrant immediate discontinuation.

Please see the full **Prescribing Information**.

Immedica pharma

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Immedica Pharma US Inc., Chicago, IL 60642

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