



Ztalmy in Saudi Arabia

The SFDA named-patient coordination pathway — indicative 2026

PAEDIATRIC NEUROLOGY · CDKL5 DEFICIENCY DISORDER

The clinical situation

Ztalmy (ganaxolone) is an FDA-approved oral suspension neuroactive steroid indicated for seizures associated with CDKL5 deficiency disorder (CDD) in patients aged 2 years and older, manufactured by Marinus Pharmaceuticals. CDD is a rare, severe, X-linked developmental and epileptic encephalopathy driven by pathogenic CDKL5 variants. Ztalmy is taken three times daily, dosed by weight. Eligibility anchors to clinical diagnosis of CDD (typically with genetic confirmation of a pathogenic CDKL5 variant) and refractory seizures, with ongoing seizure-diary tracking and liver-function monitoring under paediatric neurology supervision.

The pathway, 6 steps

- 1 Consultation with paediatric neurology.** CDKL5 genetic confirmation, clinical diagnosis of CDD, seizure history, and Ztalmy clinical rationale documented.
- 2 Baseline assessment.** Weight, seizure-frequency baseline, liver-function tests, and current antiseizure regimen recorded.
- 3 SFDA named-patient application.** Physician or hospital pharmacy files clinical rationale, genetic report, patient reference, and chain-of-custody plan.
- 4 US-side sourcing.** Reserve Meds coordinates with our US-licensed DSCSA-compliant specialty wholesale partner to secure Ztalmy from Marinus's authorised channel.
- 5 Shipment.** Chain-of-custody documentation travels with the bottle; manufacturer handling conditions apply during transport.
- 6 Arrival & dispensing.** The hospital pharmacy releases the bottle to the family with weight-based dosing and seizure-diary coaching.

Indicative economics

Reference US cash-pay range: USD 110,000–250,000 per year depending on body weight (drug-only reference; Reserve Meds provides a transparent delivered quote at intake).

Indicative first-dose timing

7–14 days from a complete SFDA application to first dispensation, once cohort intake opens. Indicative — not guaranteed.

Reserve Meds's role

Sourcing. US-licensed specialty wholesale partner, DSCSA chain-of-custody. **Documentation.** Regulatory package for your physician and SFDA review, keyed to the CDKL5 rationale. **Logistics.** Shipment coordination to the prescribing hospital

pharmacy. **Concierge case lead.** Named point of contact for the family and neurology team, coordinating long-term refills and weight-based dose adjustments. **We are a coordinator** — not the prescriber, not the dispensing pharmacy. All clinical decisions remain with your treating paediatric neurologist.

COMPOSITE EXAMPLE · PRE-LAUNCH WAITLIST

Join the Ztalmy × Saudi Arabia first-cohort waitlist. *Our concierge reaches out as we open intake.*

reservemed.com/access-guides/ztalmy-saudi-arabia.html



SCAN TO JOIN

Reserve Meds · US-based concierge for cross-border specialty medicine. We are a coordinator; we are not the prescriber and not the dispensing pharmacy. All clinical decisions remain with the treating physician. Not medical advice.

Reserve Meds is in pre-launch. Service availability is limited to our first cohort; all timelines published are indicative, not guarantees. Composite case examples only.

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