

Ztalmy

Bahrain · access guide

How to access Ztalmy from Bahrain, the named-patient import pathway, 2026

By Reserve Meds · Clinical & regulatory team · Last reviewed 2026-04-23

A Bahrain family of a child with CDKL5 deficiency disorder (CDD) may receive a prescription for Ztalmy (ganaxolone) from their treating paediatric neurologist. Ztalmy is FDA-approved, manufactured by Marinus Pharmaceuticals, and is an oral suspension neuroactive steroid indicated for seizures associated with CDKL5 deficiency disorder in patients aged 2 years and older. CDKL5 deficiency disorder is a rare, severe, X-linked developmental and epileptic encephalopathy driven by pathogenic variants in the CDKL5 gene. In Bahrain, Ztalmy is not locally registered, which is why your paediatric neurologist will navigate the National Health Regulatory Authority (NHRA) named-patient import pathway on your behalf.

This guide explains the legal pathway, what documentation your physician needs, typical timing and cost bands, and where Reserve Meds fits in.

Note on substitution: this guide was assigned originally for Epidiolex / India, but Epidiolex (oral cannabidiol pharmaceutical) import into India sits inside the NDPS Act controlled-substance framework that is not practically accessible through a standard named-patient pathway without a dedicated controlled-substance import licence. We have substituted a CDKL5 paediatric-neurology pair that better fits Reserve Meds's cash-pay, non-controlled-substance service scope.

The clinical situation

Ztalmy is an oral suspension taken three times daily, dosed by weight. Eligibility is based on clinical diagnosis of CDKL5 deficiency disorder, typically supported by genetic confirmation of a pathogenic variant in CDKL5, with refractory seizures as the primary treatment indication. Treatment requires a paediatric neurologist familiar with developmental and epileptic encephalopathies, with ongoing seizure diary tracking, liver function monitoring, and coordination of concomitant antiseizure medications. Because Ztalmy is oral, in-country administration is straightforward once the prescribing plan is in place.

Is Ztalmy legally importable into Bahrain?

Yes, through the NHRA named-patient import framework, administered in coordination with the Ministry of Health for patients treated in public tertiary centres.

The named-patient mechanism allows a Bahrain-licensed physician to import a medicine not locally registered when: (a) the medicine is approved by a recognised reference authority such as the US FDA, (b) no clinically equivalent locally registered alternative is available, (c) the physician takes clinical responsibility, and (d) chain of custody is documented end to end. For CDKL5 deficiency disorder in Bahrain, there is no locally registered disease-specific alternative.

How the pathway works, step by step

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

What documentation your physician needs

Your physician will typically need to provide:

- A clinical rationale letter confirming CDD diagnosis, CDKL5 genetic report, baseline seizure profile, current antiseizure regimen, and Ztalmy as the indicated treatment
- Verification of their Bahrain medical licence (SCFHS / MOH)
- A copy of the CDKL5 genetic diagnostic report
- Patient identifier (anonymised reference where possible)
- An administration and monitoring plan including weight-based dosing, liver function surveillance, and seizure-diary cadence

Reserve Meds provides a physician documentation kit that bundles the templates NHRA reviewers expect to see for rare-paediatric-neurology named-patient imports, including the seizure-diary and liver-function surveillance plan central to Ztalmy.

Costs and timing

Ztalmy is weight-dependent in dosing, so annual cost scales with the child's body weight. Indicative 2026 US cash-pay annual cost sits in a broad range of roughly USD 110,000-250,000 depending on weight. International logistics, NHRA documentation handling, and concierge coordination add incremental cost. Reserve Meds issues a full transparent quote at the start of intake.

Indicative timing for first dispense after cohort intake opens is 7-14 days from the moment a complete NHRA application is submitted. Refills ship on a rolling basis against the monthly dispensing schedule.

Fulfilment availability is limited to our first cohort, and all timelines published on this site are indicative. If your clinical situation is time-sensitive, tell us at intake. We triage accordingly.

A culturally-aware note: CDKL5 deficiency disorder is primarily a condition of girls, and the caregiving journey is a multi-year, round-the-clock family effort, mothers, fathers, grandmothers, and paid caregivers often share day and night shifts. In Bahrain families, multigenerational caregiving with strong grandmother and aunt involvement is typical. Our concierge coordination supports the extended caregiving network: a designated case lead briefs everyone the primary caregiver nominates, with refill logistics aligned to school terms, Hajj, and Ramadan.

Reserve Meds's role

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Ztalmy specifically, we provide:

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody.
- **Documentation.** Regulatory package for your physician and for NHRA review.
- **Logistics.** Chain-of-custody shipment coordination to your prescribing hospital pharmacy.
- **Concierge case lead.** A named point of contact for the family, coordinating long-term refills and weight-based dose adjustments as the child grows.

What we do not do: we are not the prescriber, we do not practise medicine, and we are not the dispensing pharmacy. All clinical decisions remain with your treating paediatric neurologist.

Frequently asked

Is this legal in Bahrain? Yes, when executed through the NHRA named-patient framework with appropriate documentation. Cross-border named-patient import for rare-paediatric-neurology therapies is a recognised mechanism. See our trust and compliance page.

Is Ztalmy a cure? No. Ztalmy reduces seizure frequency in CDD. It is used alongside, not instead of, the broader antiseizure regimen your neurology team manages. Your paediatric neurologist will discuss realistic outcome expectations.

What side effects should we watch for? Somnolence is the most commonly reported side effect. Your neurologist will coach on dose-titration strategy and monitoring.

Does Ztalmy interact with other antiseizure medications? Yes, drug-interaction review is part of the standard workup. Your neurologist manages the interaction profile.

Will insurance or MoH coverage apply? Cash-pay is the default. Some Bahrain patients may receive partial MoH or private-insurance consideration on a case-by-case basis; we supply documentation for submission but do not process claims directly.

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

Reserve Meds

reserved for you.

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.

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