Diacomit

Saudi Arabia · access guide

How to access Diacomit from Saudi Arabia, the named-patient import pathway, 2026

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

A Saudi Arabiai family whose child has been diagnosed with Dravet syndrome may receive a prescription for Diacomit (stiripentol) from their treating paediatric neurologist or epileptologist. Diacomit is FDA-approved as adjunctive therapy for seizures associated with Dravet syndrome in patients aged 6 months and older who are also taking clobazam. It is manufactured by Biocodex. Dravet syndrome is a severe, early-onset epileptic encephalopathy typically caused by SCN1A mutations, and Diacomit is part of a small group of therapies, alongside clobazam, cannabidiol (Epidiolex), and fenfluramine (Fintepla), that have established disease-specific efficacy. In Saudi Arabia, Diacomit may not yet be broadly registered, which is why your neurologist may be navigating a named-patient import pathway with you.

This guide explains the legal pathway, what your physician needs to provide, typical timelines, and where Reserve Meds fits in.

The clinical situation

Diacomit is available as oral capsules or oral-suspension sachets, dosed by body weight (typically 50 mg/kg/day divided into two or three doses) as an add-on to a regimen that must include clobazam. Dravet syndrome typically presents in the first year of life with prolonged febrile seizures and evolves into drug-resistant mixed seizure types; the goal of combination therapy is seizure reduction and, critically, reduction of convulsive status-epilepticus episodes. Your treating paediatric neurologist confirms the SCN1A genotype or phenotype-based Dravet diagnosis, the existing clobazam regimen, and the overall anti-seizure medication (ASM) plan.

Is Diacomit legally importable into Saudi Arabia?

Yes, through the Saudi Arabia Ministry of Public Health (MoPH) Pharmacy and Drug Control Department's named-patient import framework. The pathway allows a Saudi Arabia-licensed physician to request import of a medicine not locally registered when: (a) the medicine is approved by a recognised reference authority (FDA qualifies), (b) no locally registered alternative is clinically equivalent for the patient, (c) the physician takes clinical responsibility, and (d) chain of custody is documented.

For Diacomit specifically, the application is routine, an oral formulation with standard room-temperature handling and no REMS or controlled-substance complexity. Stiripentol is not a DEA-scheduled controlled substance.

How the pathway works, step by step

1. **Consultation with your treating paediatric neurologist.** Dravet syndrome diagnosis (genetic confirmation where available), current clobazam regimen, and the clinical rationale for Diacomit add-on.
2. **MoPH named-patient application.** Your physician files the application with MoPH Pharmacy and Drug Control Department including clinical letter, paediatric patient identifier, and product details.
3. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure the product from the manufacturer's authorised distribution chain.
4. **Shipment.** Diacomit ships at controlled room temperature; no cold-chain is required.
5. **Arrival and dosing initiation.** The treating physician initiates weight-based dosing alongside ongoing clobazam and other ASMs.

What documentation your physician needs

Your physician will typically need to provide:

- Clinical rationale letter confirming Dravet syndrome diagnosis (with SCN1A genetic testing where available), current clobazam regimen, and Diacomit as indicated adjunctive therapy
- Verification of Saudi Arabia medical licence
- Paediatric patient identifier (often anonymised for privacy)
- Weight-based dosing calculation and projected monthly supply
- Consent documentation from parents or legal guardians

Reserve Meds provides a physician documentation kit that bundles the templates MoPH reviewers expect to see for paediatric rare-disease applications.

Costs and timing

Diacomit's US cash-pay drug-only reference price sits in a broad indicative range, the total monthly cost is weight-dependent but typically falls in the range of USD 3,000-5,000 per month at maintenance dosing for paediatric patients. Shipment, documentation, and concierge coordination add incremental cost; Reserve Meds issues a full transparent quote at the start of intake. Indicative range.

Indicative timing for the first dispensed supply after cohort intake opens is 7-14 days from the moment a complete application is submitted. Refills ship on a rolling basis.

Fulfillment 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.

Reserve Meds's role

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Diacomit 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 MoPH review.
- **Logistics.** Controlled-room-temperature shipment coordination, formulation-specific (capsule vs suspension).
- **Concierge case lead.** A named point of contact for your family.

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

Frequently asked

Is this legal in Saudi Arabia? Yes, when executed through the MoPH named-patient framework with appropriate documentation. The pathway is commonly used for paediatric rare-disease therapies.

Does my child have to be on clobazam? Yes, Diacomit's approved indication specifies use in patients taking clobazam. Your neurologist will have established clobazam first.

What about cultural-family context in Saudi Arabia? Paediatric rare-disease care in Saudi Arabia is typically led by a paediatric neurologist at Sidra Medicine or Hamad Medical Corporation, often in close family coordination. Reserve Meds is accustomed to working with family decision-makers and will coordinate with the lead physician and the family point-of-contact as you direct.

Will private insurance cover this? Cash-pay is the default. Some Saudi Arabia private insurers reimburse paediatric rare-disease named-patient imports on escalated review; we supply documentation for your submission but do not process insurance 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.

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