Xdemvy access in the UAE: the MOHAP and EDE named-patient pathway

How patients in the United Arab Emirates access Xdemvy (lotilaner ophthalmic solution 0.25%) for Demodex blepharitis when no equivalent product is locally registered.

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1. Quick orientation

Xdemvy is the brand name for lotilaner ophthalmic solution 0.25%, a topical ophthalmic small-molecule ectoparasiticide developed and commercialised by Tarsus Pharmaceuticals. It is not a biologic, not an antibiotic, and not a steroid. The mechanism is selective antagonism of the Demodex mite gamma-aminobutyric acid-gated chloride channel, producing parasiticidal effect against the mite rather than treating downstream inflammation alone. The US Food and Drug Administration approved Xdemvy on 25 July 2023 for the treatment of Demodex blepharitis in adults. It is the first and only FDA-approved therapy that directly targets the underlying mite infestation. In the United Arab Emirates, Xdemvy is not locally registered as of the date of this page. UAE patients with chronic, recalcitrant Demodex blepharitis reach the medicine through the federal unregistered-medicine import permit administered by MOHAP and, from 29 December 2025, through the Emirates Drug Establishment (EDE) portal at ede.gov.ae. Reserved for you.

2. Why UAE patients need Xdemvy via the named-patient pathway

The UAE pharmaceutical regulatory framework recognises three structural access gaps: registered but not stocked at a particular hospital pharmacy, registered for a different indication, and not registered locally at all. Xdemvy sits squarely in the third pattern. Tarsus Pharmaceuticals is the sole commercial owner of the asset, and as of May 2026 no centralised European Medicines Agency authorisation, UK MHRA national authorisation, Health Canada Notice of Compliance, or PMDA Japan authorisation has been confirmed in public regulatory records. Within the GCC and broader MENA region, no UAE MOHAP marketing authorisation has been confirmed.

Three convergent factors route UAE Xdemvy access through the named-patient pathway. First, Demodex blepharitis is highly prevalent globally and is estimated to account for roughly two-thirds of all blepharitis cases worldwide, so the affected UAE patient population is substantial. Second, Xdemvy is the first and only FDA-approved drug that directly targets the underlying Demodex mite, and no equivalent locally registered parasiticidal ophthalmic product exists in the UAE. Local ophthalmology has historically relied on lid hygiene, hypochlorous acid sprays, tea tree oil derivatives, and off-label antiparasitic compounds, none of which carry a regulator-endorsed Demodex blepharitis indication. Third, the UAE patient pursuing Xdemvy typically presents with chronic, recalcitrant Demodex blepharitis confirmed on slit-lamp examination, has failed adjunctive measures, and has a UAE-licensed ophthalmologist willing to write the cross-border prescription. The case file documents the slit-lamp diagnosis, prior therapy failures, and the rationale for sourcing the only directly indicated product.

3. The MOHAP and EDE named-patient pathway for Xdemvy

The federal pathway for a UAE-licensed ophthalmologist to obtain Xdemvy is the unregistered-medicine import permit, historically administered by MOHAP and, from 29 December 2025, through the EDE portal under Federal Decree-Law No. 38 of 2024. The framework allows hospitals and licensed pharmaceutical establishments to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority (the US FDA, EMA, MHRA, PMDA

Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable. The Xdemvy case file rests on the absence of any locally registered FDA-equivalent product for the specific indication of Demodex blepharitis.

A complete application typically includes:

- A clinical justification letter from the treating ophthalmologist or optometrist (UAE-licensed, with prescribing authority in the emirate of the dispensing facility)
- The treating physician's UAE medical license verification (MOHAP, DHA, DOH, or Sharjah Health Authority, depending on practice location)
- An anonymised patient identifier where the EDE submission allows
- Full product details: Xdemvy, lotilaner ophthalmic solution 0.25%, 5 mL multi-dose bottle, manufacturer Tarsus Pharmaceuticals, quantity sufficient for the 6-week course (two 5 mL bottles, 10 mL total)
- The destination dispensing pharmacy name, license number, and pharmacy in charge
- A chain-of-custody plan describing how the ambient ophthalmic solution will move from the US specialty pharmacy through the importer to the dispensing pharmacy

The clinical-justification angle for Xdemvy is documented diagnosis and failure of adjunctive measures. The treating ophthalmologist documents Demodex blepharitis on slit-lamp examination (collarettes at the base of the eyelashes, lid margin telangiectasia, eyelid debris, and symptomatic ocular irritation), reports the prior interventions and their outcomes (lid hygiene, hypochlorous acid lid sprays, in-office microblepharoexfoliation, off-label tea tree oil derivatives), and states that no equivalent FDA-approved or locally registered parasiticidal ophthalmic product exists for this indication. Approval timelines for routine UAE cases are typically 5 to 15 business days. Xdemvy cases are generally lower clinical acuity than oncology cases and frequently fall in the shorter portion of that range.

4. Where Xdemvy gets dispensed in the UAE

Xdemvy is a topical ophthalmic solution. It does not require infusion infrastructure, cold-chain storage, or specialised dispensing equipment. The dispensing requirement is a UAE-licensed hospital outpatient pharmacy or specialised import pharmacy, paired with a UAE-licensed ophthalmologist or optometrist with prescribing authority supervising the case. Because the 6-week course requires patient-administered twice-daily instillation rather than facility administration, the case is structured around a single dispense to the patient with prescriber follow-up at the end of the course.

UAE institutions and hospital pharmacies with ophthalmology services and named-patient import infrastructure include the multispecialty hospitals identified in the country module, among them Cleveland Clinic Abu Dhabi (M42 group), Sheikh Khali