Xdemvy access in Egypt: the EDA personal-import named-patient pathway

How adult patients in Egypt access Xdemvy (lotilaner ophthalmic solution, 0.25%) for Demodex blepharitis when no equivalent locally registered parasiticidal ophthalmic product exists, with a finite 6-week course and mid-tier specialty pricing.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.

1. Quick orientation

Xdemvy is the brand name for lotilaner ophthalmic solution, 0.25%, a topical ophthalmic small-molecule ectoparasiticide developed and commercialized by Tarsus Pharmaceuticals. The mechanism is selective antagonism of the Demodex mite GABA-gated chloride channel, producing a parasiticidal effect against the underlying 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 Demodex mite infestation. In Egypt, Xdemvy is not registered with the Egyptian Drug Authority (EDA); patients reach the medicine through EDA Personal Importation under Law No. 151 of 2019. Reserved for you.

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

Demodex blepharitis is highly prevalent globally and is estimated to account for roughly two-thirds of all blepharitis cases worldwide. Egyptian ophthalmology has historically managed Demodex blepharitis with lid hygiene, hypochlorous acid sprays, tea tree oil derivatives, and off-label antiparasitic compounds, none of which carries a regulator-endorsed Demodex blepharitis indication. Xdemvy sits firmly in the third pattern of EDA access gap: not registered locally at all. The product holds its primary marketing authorization in the United States; no confirmed centralized EMA marketing authorization for lotilaner ophthalmic 0.25% has been identified in public regulatory records as of May 2026, and no confirmed UK MHRA, Health Canada Notice of Compliance, PMDA Japan authorisation, MOHAP UAE, SFDA Saudi Arabia, EDA Egypt, CDSCO India, or DRAP Pakistan marketing authorization has been identified in public records.

Egyptian ophthalmology programmes at the major academic and private specialty centres see chronic, recalcitrant Demodex blepharitis on slit-lamp examination, and patients who have failed adjunctive measures with lid hygiene, hypochlorous acid sprays, and tea tree oil derivatives, and who have an ophthalmologist willing to write the cross-border prescription, are the typical Xdemvy case profile. The case file documents diagnosis on slit-lamp examination with collarette burden description, prior therapy failures, and the rationale for sourcing the only directly indicated product. Substitution is not a clinical match; Xdemvy is the only FDA-approved Demodex-directed parasiticidal ophthalmic drop, and there is no locally registered equivalent in Egypt.

3. The EDA named-patient pathway for Xdemvy

The Egyptian Drug Authority was created by Law No. 151 of 2019, issued 25 August 2019 in the Official Gazette No. 34 bis (A), with executive regulations under Prime Minister Decision No. 777 of 2020 on 29 March 2020. EDA is a public service authority affiliated to the Prime Minister and consolidates functions previously held by the National Organization for Drug Control and Research (NODCAR), the National Organization for Research and Control of Biopharmaceuticals (NORCB), and the Ministry of Health's Central Administration of Pharmaceutical Affairs (CAPA). EDA permits the importation of unregistered medicines for a specific patient under defined conditions, most importantly where no equivalent

registered product is available locally. This is the pathway commonly referred to as Personal Importation, sometimes described in EDA correspondence as Special Access or Compassionate Use for unregistered drugs.

The standard application package for Xdemvy includes the clinical justification letter from the treating ophthalmologist, on hospital letterhead, original and stamped, stating the Demodex blepharitis diagnosis (slit-lamp confirmation of collarettes at the base of the eyelashes is the principal diagnostic finding), the chronic and recalcitrant nature of the case where applicable, the prior therapies attempted (lid hygiene, hypochlorous acid lid sprays, tea tree oil derivatives, in-office microblepharoexfoliation) and the specific reason a directly indicated Demodex-targeted parasiticidal product is required; a recent prescription specifying brand name (Xdemvy), generic name (lotilaner ophthalmic solution 0.25%), pack size (5 mL multi-dose bottle), and quantity required (two 5 mL bottles for a complete 6-week course); a patient identifier (copy of the national ID card or passport for the adult patient, as Xdemvy is not approved for pediatric patients under 18); the treating physician's Egyptian Medical Syndicate (EMS) membership number and Ministry of Health licence reference; product details (Tarsus Pharmaceuticals, Inc. as US NDA holder, country of origin, FDA NDA 217603 approval July 2023, room-temperature storage condition); the destination dispensing facility licence; and a chain-of-custody plan.

The clinical-justification angle that matters most for Xdemvy is the slit-lamp confirmation of Demodex blepharitis with collarette burden documented, paired with the prior-therapy-failure narrative. The letter cites the Saturn-1 (Yeu et al., Cornea 2022) and Saturn-2 (Gaddie et al., Ophthalmology 2023) phase 3 randomised vehicle-controlled trials, which enrolled more than 800 patients combined and reported no serious treatment-related adverse events with the most common adverse reaction being instillation site stinging and burning in approximately 10 percent of patients. Because Xdemvy is a finite 6-week course rather than chronic therapy, the application typically requests sufficient supply for the complete course (two 5 mL bottles), with re-treatment for recurrence decided by the treating ophthalmologist on a case-by-case basis. Routine EDA personal-import authorisations for well-documented cases are typically processed in a 3 to 6 week window once a complete package is submitted, with complex or biologic cases extending further. Xdemvy as an ambient ophthalmic small-molecule is generally on the simpler end of the EDA workflow. EDA reserves discretion at every step. Reserve Meds does not promise EDA timelines and is not the filer.

4. Where Xdemvy gets dispensed in Egypt

Xdemvy is supplied as a sterile ophthalmic solution in a 5 mL multi-dose bottle. The product is stable at controlled room temperature, 20 to 25 degrees Celsius, with permitted excursions between 15 and 30 degrees Celsius. Refrigeration at 2 to 8 degrees Celsius is permitted but not required. There is no reconstitution step and no light-protection requirement beyond the supplied bottle and carton. The dispensing requirement in Egypt is an EDA-licensed hospital outpatient pharmacy or licensed specialty importer pharmacy, paired with a treating ophthalmologist with EMS registration and Ministry of Health licence. Xdemvy is patient-administered (one drop in each eye twice daily for 6 weeks) and does not require in-clinic administration.

Egyptian institutions with strong ophthalmology services able to anchor an Xdemvy case include Cairo University Hospitals (Kasr Al Ainy), with the Faculty of Medicine ophthalmology department and an institutional import workflow; Ain Shams University Hospitals, with broad specialty ophthalmology services; the ophthalmology services at Dar Al Fouad Hospital in 6th of October City, Giza, As-Salam International Hospital in Cairo, and the Cleopatra Hospitals Group. For physicians at smaller hospitals or outpatient ophthalmology clinics, the practical route is partnering with a Cairo-based licensed specialty importer that handles the EDA filing, customs clearance, and final delivery to a licensed dispensing facility, with the clinical justification still coming from the treating ophthalmologist. The case clinical acuity is lower than oncology cases, but the regulatory pathway is the same.

5. Real cost picture for Xdemvy in Egypt

Reserve Meds quotes Xdemvy cases in USD and accepts USD wire transfers. The EGP has lost more than 70 percent of its value against the US dollar since early 2022, with the USD/EGP rate near 52 to 53 in May 2026. Three line items frame the economics.

First, drug cost. The US wholesale acquisition cost range for a complete 6-week course of Xdemvy (10 mL total, two 5 mL bottles) is approximately USD 1,850 to USD 2,034 at the cash list price per pharmacy pricing aggregators including GoodRx and pharmacy-pricing trade references in 2026. A single 5 mL bottle list price runs approximately USD 600 to USD 1,000 depending on the pharmacy and the date of the price reference. Position is mid-tier specialty rather than ultra-high-cost biologic; a single course of Xdemvy is one to two orders of magnitude below per-course pricing for advanced oncology biologics or rare-disease enzyme replacement therapies. At the May 2026 EGP/USD rate, the full course corresponds to approximately EGP 97,000 to EGP 107,000.

Second, international logistics. Xdemvy is an ambient ophthalmic small-molecule. Standard pharmaceutical-grade ambient shipping with documented chain of custody is sufficient. International logistics from the US source to Cairo International Airport typically runs USD 400 to USD 1,000 (approximately EGP 21,000 to EGP 53,000) depending on volume and route. Because the full 6-week course fits in a single shipment, most Xdemvy cases are single-shipment and do not carry repeat-shipment logistics overhead.

Third, Egyptian regulatory documentation handling fees on the dispensing facility side and the Reserve Meds concierge fee, itemised on the firm quote and never bundled. On the insurance side, Bupa Egypt, AXA Egypt, MetLife Egypt, Allianz Egypt, Misr Insurance, and the other Egyptian insurers each assess named-patient imports case by case. The Universal Health Insurance Authority (UHIA) does not currently cover most specialty imports. Cash-pay is the dominant posture. The mid-tier specialty position means many Egyptian patients fund Xdemvy entirely out of pocket without diaspora coordination, which is more typical of the ultra-high-cost oncology and rare-disease cases.

6. Typical timeline for Xdemvy in Egypt

Xdemvy is an ambient ophthalmic small-molecule, which is on the simpler end of the EDA workflow. End-to-end, a typical Xdemvy case in Egypt runs as follows: 24 to 48 hours from intake to eligibility confirmation by Reserve Meds; 3 to 7 days for the treating ophthalmologist's team to assemble the personal-import application with the slit-lamp diagnostic documentation, the prior-therapy-failure narrative, and the dispensing facility documentation; 3 to 6 weeks for routine EDA review on a well-documented case, with shorter ranges typical for simpler ambient ophthalmic products though EDA reserves discretion; 3 to 5 days for US sourcing through the Tarsus authorized specialty pharmacy network (AllianceRx Walgreens Pharmacy, CVS Specialty, and additional ophthalmology-aligned specialty pharmacies), release documentation, and ambient courier shipment to Cairo International Airport; 1 to 2 days for customs clearance under the EDA authorisation; and final verification and dispense at the hospital outpatient pharmacy or specialty importer pharmacy. Because Xdemvy is a finite 6-week course, most cases are single-shipment which simplifies coordination versus chronic monthly cadence products.

7. What your physician needs to provide

The clinical justification letter is the cornerstone of the EDA personal-import application for Xdemvy. The treating Egyptian ophthalmologist documents the Demodex blepharitis diagnosis on slit-lamp examination, with explicit reference to collarettes at the base of the eyelashes as the principal diagnostic finding, the chronic and recalcitrant nature of the case where applicable, the duration of disease, and the prior therapies attempted and failed (lid hygiene, hypochlorous acid lid sprays, tea tree oil derivatives, in-office microblepharoexfoliation, and any off-label antiparasitic compounds used). The letter explicitly notes that no equivalent locally registered Demodex-directed parasiticidal ophthalmic product exists in Egypt, citing Xdemvy as the first and only FDA-approved therapy for Demodex blepharitis, with reference to Saturn-1 and Saturn-2 randomised vehicle-controlled trial data on collarette cure and mite eradication rates.

The letter states the dosing regimen as one drop in each eye, twice daily (approximately 12 hours apart), for 6 weeks, with instructions on administration mechanics from the package insert: wash hands before instillation; remove contact lenses prior to instillation and wait at least 15 minutes before reinsertion; instill one drop in each eye and avoid bottle tip contact with the eye or eyelid; continue the full 6-week course even if symptoms resolve earlier. Treatment is a finite course, not chronic indefinite therapy. The monitoring plan is minimal: there are no required laboratory studies, no required electrocardiogram, and no required pre-treatment screening assays; clinical follow-up is on the prescriber's standard

ophthalmology cadence, typically a check at the end of the 6-week course to evaluate collarette resolution and symptom response. The letter is co-filed with the physician's EMS membership and Ministry of Health licence reference, the dispensing facility licence, the requested pack count (two 5 mL bottles for the complete course), and the chain-of-custody plan from the US Tarsus-authorized specialty pharmacy through to the dispensing pharmacy in Egypt. Pharmacovigilance reporting through the Egyptian Pharmacovigilance Center (EPVC) using Yellow Card or CIOMS forms applies through the course of therapy and is the prescribing ophthalmologist's obligation.

8. Common questions about Xdemvy in Egypt

Will Bupa Egypt, AXA Egypt, MetLife, or Allianz cover the cost? Each insurer assesses named-patient imports case by case. Some plans reimburse a percentage when the drug treats a covered indication; the mid-tier specialty position of Xdemvy makes the per-course cost more tractable for partial reimbursement than ultra-high-cost biologics. We supply the documentation an insurer needs to assess. The claim filing remains with the patient or the hospital.

Does UHIA cover specialty imports like Xdemvy? Not as a general rule. The Universal Health Insurance rollout under Law No. 2 of 2018 is phased through to 2032. For most named-patient specialty imports in 2026, UHIA coverage is not the funding path.

Why Xdemvy versus tea tree oil, lid hygiene, or hypochlorous acid sprays? The clinical rationale is mechanism specificity. Lid hygiene reduces bacterial load and debris, tea tree oil has variable anti-mite activity with significant tolerability concerns at therapeutic concentrations, and neither demonstrates the collarette cure and mite eradication rates documented for lotilaner in the Saturn-1 and Saturn-2 randomised vehicle-controlled trials. The decision rests with the treating ophthalmologist.

What is the safety profile? Saturn-1 and Saturn-2 enrolled more than 800 patients combined and reported no serious treatment-related adverse events. The most common adverse reaction was instillation site stinging and burning, reported in approximately 10 percent of patients. Other ocular adverse reactions including chalazion/hordeolum and punctate keratitis were reported in less than 2 percent of patients. The product is generally well tolerated.

What if my Demodex blepharitis returns after the 6-week course? There is no defined re-treatment interval in the label, and decisions on a second course in cases of recurrence are made by the treating ophthalmologist on a case-by-case basis. If a second course is indicated, a new personal-import application is filed at that time with the recurrence documentation.

Is Xdemvy approved for my child? No. Xdemvy is approved for adults aged 18 and older with Demodex blepharitis. It is not approved for pediatric patients under 18, and Reserve Meds does not coordinate off-label pediatric use. Children's eye conditions route to a pediatric ophthalmologist for age-appropriate options.

9. Where Reserve Meds fits in Xdemvy cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating ophthalmologist, EDA, your dispensing pharmacy, or your insurer, and we do not act as an importer of record in Egypt. What we do for an Xdemvy case is verify eligibility within 24 to 48 hours including slit-lamp Demodex blepharitis confirmation and prior-therapy documentation; supply your ophthalmologist's team with a documentation kit referencing the Tarsus prescribing information, the July 2023 FDA NDA 217603 approval, the Saturn-1 and Saturn-2 trial data, and the EDA Personal Importation application format; align the US-side sourcing through the Tarsus authorized specialty pharmacy network with the Egyptian dispensing facility; coordinate the ambient courier shipment under chain-of-custody documentation to Cairo International Airport; and provide a single named coordinator across the case, in Arabic on the patient side and English on the family side where the family is split across the diaspora. The case pattern is typically lower clinical acuity than oncology cases and the finite 6-week course means most cases are single-shipment. No prior Reserve Meds case experience predates this page; standard NPP coordination applies.

10. Next step

If your Egyptian ophthalmologist has confirmed Demodex blepharitis on slit-lamp examination and recommends Xdemvy (lotilaner ophthalmic solution, 0.25%), start the request and we will reach out within 24 to 48 hours.

Reserved for you.

Review & oversight. Content on this page is reviewed by Reserve Meds's clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. Review methodology ›

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