Xdemvy access in India: the CDSCO Rule 36 named-patient pathway

How patients in India access Xdemvy (lotilaner ophthalmic solution 0.25%) for Demodex blepharitis when no equivalent locally registered parasiticidal ophthalmic product exists.

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 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 India, Xdemvy is not registered with the Central Drugs Standard Control Organization (CDSCO) as of May 2026, and no equivalent locally registered Demodex blepharitis indication exists for an ophthalmic parasiticidal product. Patients with chronic recalcitrant Demodex blepharitis confirmed on slit-lamp examination reach the medicine through Rule 36 of the Drugs and Cosmetics Rules 1945, with the office of the Drugs Controller General of India (DCGI) issuing Form 12B against a complete Form 12A application. Reserved for you.

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

India has the deepest tertiary specialty hospital network of any Reserve Meds priority country and one of the largest ophthalmology training and practice bases in the world. Yet for a specific group of US-sourced specialty ophthalmic drugs, Indian patients hit an access wall. Xdemvy sits firmly in the third pattern of access gap identified across CDSCO Rule 36 work: not registered locally at all.

Demodex blepharitis is highly prevalent globally and is estimated to account for roughly two-thirds of all blepharitis cases worldwide. Indian outpatient ophthalmology and optometry clinics see this case-mix routinely. Xdemvy is the first and only FDA-approved drug that directly targets the underlying mite. No equivalent locally registered parasiticidal ophthalmic product exists in India. Local ophthalmology has historically relied on lid hygiene, hypochlorous acid sprays, tea tree oil derivatives, and off-label antiparasitics, none of which carry a regulator-endorsed Demodex blepharitis indication and none of which demonstrates the collarette cure and mite eradication rates documented for lotilaner in the Saturn-1 and Saturn-2 phase 3 trials.

Patients pursuing Xdemvy through Rule 36 typically present with chronic, recalcitrant Demodex blepharitis confirmed on slit-lamp examination (collarettes at the eyelash base are the pathognomonic finding), have failed adjunctive measures, and have an ophthalmologist willing to write the cross-border prescription. The case file documents diagnosis, prior therapy failures, and the rationale for sourcing the only directly indicated product. The clinical-acuity profile is lower than oncology or rare-disease cases, but the regulatory pathway is the same.

3. The CDSCO Rule 36 named-patient pathway for Xdemvy

The legal foundation for personal import of unregistered medicines into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits import of a small quantity of a drug for the exclusive personal use of a named patient, with the legal basis sitting under Section 10 of the Drugs and Cosmetics Act 1940.

Form 12A is the application for a permit, made under the second proviso to Rule 36. Form 12B is the permit itself, issued by the office of the DCGI at FDA Bhawan, Kotla Road, New Delhi, or by designated CDSCO Port Offices. The application is

accompanied by a prescription from a Registered Medical Practitioner (RMP) whose National Medical Commission (NMC) registration number appears on the prescription, with the quantity required for treatment. The quantity of any single drug imported shall not exceed one hundred average doses per application, which is well above the requirement for a complete Xdemvy course.

For straightforward Rule 36 cases of this kind, the filing party is typically the patient or the family directly through the office of the DCGI in New Delhi or a designated port office, working with a CDSCO-licensed specialty importer that handles the chain-of-custody documentation. Institutional Compassionate Use is generally not required for a topical ophthalmic case, because Xdemvy is FDA-approved for a defined indication in adults and the Rule 36 personal-import route is the natural fit.

A complete CDSCO application for Xdemvy typically includes:

- A clinical justification letter (Demodex blepharitis diagnosis with slit-lamp evidence of collarettes, prior therapies tried and failed, the specific reason this product is required)
- The treating ophthalmologist's NMC registration number and state-council registration where required
- A patient identifier and supporting medical records (slit-lamp photographs where available)
- Product details: Xdemvy, lotilaner ophthalmic solution 0.25%, Tarsus Pharmaceuticals, 5 mL multi-dose bottle, two bottles to cover the 6-week course
- The dispensing facility's drug licence (hospital ophthalmology outpatient pharmacy or specialty importer wholesale licence)
- A chain-of-custody plan from the US Tarsus-network specialty pharmacy through to the dispensing pharmacy in India

The clinical-justification angle that matters most for Xdemvy is slit-lamp confirmation of Demodex blepharitis and the failure of adjunctive measures. The treating ophthalmologist documents collarette burden, symptom history, and explicitly notes that no locally registered ophthalmic parasiticidal product exists for this indication in India. The 6-week finite course (two 5 mL bottles) generally fits within one Form 12A application without complication. CDSCO published guidance states the Form 12B permit is issued on a priority basis, typically within one to two days for routine applications where the documentation is complete.

4. Where Xdemvy gets dispensed in India

Xdemvy is a topical ophthalmic small-molecule solution, room-temperature stable at 20 to 25 degrees Celsius with permitted excursions between 15 and 30 degrees Celsius. It does not require infusion infrastructure, cold chain, or in-clinic administration. The dispensing requirement is a CDSCO-licensed hospital outpatient pharmacy or licensed specialty importer, paired with an NMC-registered ophthalmologist supervising the case.

Indian tertiary institutions that handle named-patient ophthalmology imports include the All India Institute of Medical Sciences (AIIMS), New Delhi, whose Dr. R.P. Centre for Ophthalmic Sciences is the apex public-sector ophthalmology centre; Apollo Hospitals at Chennai, Delhi, Bangalore, Hyderabad, and Kolkata with dedicated international patient services and large ophthalmology departments; Fortis Healthcare flagship sites at Gurgaon, Mumbai, and Bangalore; Medanta The Medicity, Gurgaon, with established multi-specialty workflow; Kokilaben Dhirubhai Ambani Hospital, Mumbai; Christian Medical College (CMC) Vellore, with a globally recognised ophthalmology department; and Manipal Hospitals, Bangalore. India also has a network of leading dedicated eye-care institutions including Aravind Eye Care System, LV Prasad Eye Institute, and Sankara Nethralaya, which routinely manage Demodex blepharitis caseloads.

For patients of community-based ophthalmologists or optometrists, the practical route is to work through one of the centres above for the documentation co-sign, or through a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore that handles the Form 12A filing on behalf of the prescribing ophthalmologist.

5. Real cost picture for Xdemvy in India

Costs sit in INR with the rupee floating against the US dollar. In May 2026 the USD/INR rate is in the 94 to 95 range. Three line items frame the case 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, per pharmacy pricing aggregators including GoodRx in 2026. A single 5 mL bottle list price runs approximately USD 600 to USD 1,000 depending on the pharmacy. That corresponds to roughly INR 1.74 to INR 1.93 lakh for a full course at the prevailing exchange rate. Position relative to the broader specialty-medication landscape is mid-tier specialty rather than ultra-high-cost biologic. A single Xdemvy course sits one to two orders of magnitude below per-course pricing for advanced oncology biologics or rare-disease enzyme replacement therapies, which keeps the cash-pay decision more accessible for many Indian families.

Second, international logistics. Xdemvy is an ambient ophthalmic solution. International logistics for an ambient shipment to India typically runs USD 400 to USD 1,500 (approximately INR 38,000 to INR 1.4 lakh) depending on destination city and urgency window. No gel packs, no temperature loggers, no quarantine risk. Because the 6-week course is contained in two bottles, a single shipment covers a typical case.

Third, regulatory and coordination. GST on most life-saving medicines is 5 percent; specific HSN code and exemption status of each Xdemvy shipment are confirmed at the documentation stage. On the insurance side, Star Health and Allied Insurance, HDFC ERGO, ICICI Lombard, and Niva Bupa each assess named-patient imports case by case and none reimburses a Rule 36 personal import as a standard line item, particularly for a topical ophthalmic indication that traditionally has not attracted ophthalmic specialty cover. CGHS provides for life-saving medicines not in the standard formulary to be considered by an Expert Committee on a case-by-case basis, with stricter constraints on drugs not approved by DCGI. Cash-pay is the default posture and is operationally straightforward at the Xdemvy price point.

6. Typical timeline for Xdemvy in India

CDSCO's published guidance states the Form 12B permit is issued on a priority basis, typically within one to two days for routine applications where the documentation is complete. Xdemvy is an ambient ophthalmic small-molecule product, which removes the cold-chain transit window from the timeline. End-to-end, a typical Xdemvy case in India runs as follows: 24 to 48 hours from intake to eligibility confirmation by Reserve Meds; 3 to 5 days for the treating ophthalmologist and the hospital pharmacy or specialty importer to assemble the application and slit-lamp documentation; one to two business days for routine DCGI review of a complete Form 12A; 3 to 5 days for US sourcing through the Tarsus-network specialty pharmacy, release documentation, and ambient courier shipment; 1 to 2 days for customs clearance under the Form 12B permit; and final verification and dispense at the hospital pharmacy. The full 6-week course (two 5 mL bottles, one drop in each eye twice daily) is a finite treatment cycle. There is no defined re-treatment interval in the label; second-course decisions in cases of recurrence are made by the treating clinician on a case-by-case basis.

7. What your physician needs to provide

The clinical justification letter is the cornerstone of the Form 12A application for Xdemvy. The treating Indian ophthalmologist documents the diagnosis as Demodex blepharitis in an adult, with slit-lamp confirmation of collarettes at the eyelash base (the pathognomonic finding) and a symptom history of itching, redness, foreign-body sensation, and lash misdirection where applicable; itemises prior therapies tried and failed (lid hygiene, warm compresses, hypochlorous acid sprays, tea tree oil derivatives, in-office microblepharoexfoliation, off-label oral or topical antiparasitics); states the reason a locally registered alternative is not available (Xdemvy is the only FDA-approved therapy that directly targets the underlying Demodex mite, and no equivalent regulator-endorsed Demodex blepharitis indication exists in India); states the planned dosing regimen as one drop in each eye twice daily, approximately 12 hours apart, for a full 6-week finite course, with the full course continued even if symptoms resolve earlier per the label; and describes the monitoring plan, which is minimal for a topical ophthalmic ectoparasiticide (no required laboratory studies, no required electrocardiogram, no pre-treatment

screening assays; routine ophthalmology cadence with 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 NMC registration number and state-council registration where required, the dispensing facility's drug licence (hospital outpatient pharmacy or specialty importer wholesale licence), the requested pack and quantity (Xdemvy, lotilaner ophthalmic solution 0.25%, 5 mL multi-dose bottle, two bottles to cover the 6-week course), and the chain-of-custody plan describing how the medicine will move from the US Tarsus-network specialty pharmacy through to the dispensing pharmacy in India. Pharmacovigilance Programme of India (PvPI) reporting through the Indian Pharmacopoeia Commission applies for the duration of therapy and is the prescribing physician's obligation, though serious adverse events in the Saturn-1 and Saturn-2 trials were absent and the safety profile is generally well tolerated.

8. Common questions about Xdemvy in India

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover the cost? Each insurer assesses named-patient imports case by case. None of the major private insurers reimburse a Rule 36 personal import as a standard line item, and topical ophthalmic indications have historically attracted limited ophthalmic-specialty cover in any case. At the Xdemvy price point, cash-pay is generally operationally straightforward.

Will my CGHS or ESIC entitlement cover this? CGHS provides for life-saving medicines not in the standard formulary to be considered by an Expert Committee under Special DG (DGHS) on a case-by-case basis, with stricter constraints on drugs not approved by DCGI. ESIC's formulary is narrower. Demodex blepharitis is not typically classed as a life-saving condition, so reimbursement is unlikely to be granted.

Can my community-based ophthalmologist's letter be enough, or do I need an AIIMS-level signature? Any Registered Medical Practitioner with a valid NMC registration number can support a Form 12A application. Community-based ophthalmologists routinely sign these letters; the practical route for many patients is the community ophthalmologist working with a CDSCO-licensed specialty importer that handles the filing.

What is the safety profile? The Saturn-1 and Saturn-2 pivotal phase 3 trials 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 relative to the inflammation it is intended to resolve.

Why this drug versus tea tree oil or lid hygiene? 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 randomized vehicle-controlled trials. The decision rests with the treating ophthalmologist.

Is Xdemvy a controlled substance? No. Xdemvy is not on the US DEA schedule and is not a controlled substance under Indian law. Narcotics Control Bureau coordination does not apply. The standard Rule 36 Form 12A and Form 12B permit is the operative framework.

9. Where Reserve Meds fits in Xdemvy cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating ophthalmologist, the DCGI, the dispensing hospital pharmacy or licensed importer, or your insurer. What we do for an Xdemvy case is verify eligibility within 24 to 48 hours; supply your physician's team with a documentation kit referencing the Tarsus prescribing information, the slit-lamp diagnosis criteria, and the Form 12A application format; align the US-side sourcing through DSCSA-compliant Tarsus-network specialty pharmacy with the Indian dispensing pharmacy or specialty importer; coordinate the ambient courier shipment under chain-of-custody documentation; and provide a single named coordinator across the case. Because Xdemvy is a finite 6-week course, most cases are single-shipment, which simplifies coordination

relative to chronic monthly cadence products. No prior Reserve Meds case experience predates this page; standard NPP coordination applies.

10. Next step

If your Indian ophthalmologist has confirmed Demodex blepharitis on slit-lamp examination and recommends Xdemvy, start the request and we will reach out within 24 to 48 hours.

Reserved for you.

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