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

How patients in India legally obtain Ubrelvy (ubrogepant), the first oral CGRP receptor antagonist for acute migraine, when it is not registered with the Central Drugs Standard Control Organization.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team. This page describes the personal-import pathway for Ubrelvy in India for adult patients with episodic migraine where local oral options have failed or are not appropriate.

Section 1. Quick orientation

Ubrelvy is the brand name for ubrogepant, an oral small-molecule calcitonin gene-related peptide receptor antagonist in the gepant class, FDA-approved in December 2019 for the acute treatment of migraine with or without aura in adults. It is not registered with the Central Drugs Standard Control Organization (CDSCO) for commercial sale in India. For adult patients in India whose treating neurologist has selected ubrogepant as the right next step, typically because triptans have failed, are contraindicated, or are not tolerated, the lawful access route is the personal-importation permit under Rule 36 of the Drugs and Cosmetics Rules 1945, applied for on Form 12A and issued on Form 12B by the office of the Drugs Controller General of India. Reserve Meds coordinates the US-side sourcing, documentation kit, and international logistics under a single named coordinator. The clinical decision remains with your physician. **Reserved for you.**

Section 2. Why India patients need Ubrelvy through a named-patient pathway

India has the largest tertiary specialty hospital network of any Reserve Meds priority country and Indian manufacturers supply a significant share of the world's generic medicines. Yet for a defined set of US-sourced specialty originator products, families in India still hit an access wall. Three structural gaps recur in Indian patient cases: drugs registered but not stocked at the dispensing pharmacy on the day therapy is to start, drugs registered for a different indication than the one being treated, and drugs not registered locally at all. Ubrogepant falls firmly in the third category.

AbbVie, which acquired the original developer Allergan in May 2020, has not filed Ubrelvy with the CDSCO. The drug is not stocked through retail pharmacy chains, hospital formularies, or import-pharmacy catalogues anywhere in India. Patients reading about gepants in international migraine literature, patients whose neurologists at AIIMS, Apollo, Fortis, Medanta, or other major Indian academic centres have specifically recommended an oral CGRP receptor antagonist, and patients returning to India from US treatment with an established response to Ubrelvy all encounter the same reality: no local commercial source exists. The registration gap is durable.

AbbVie has not indicated CDSCO filing on its near-term portfolio plan, and the Rule 36 personal-importation route is therefore the only lawful pathway to authentic US-supplied Ubrelvy in India.

Section 3. The CDSCO Rule 36 named-patient pathway for Ubrelvy

The legal foundation for personal import of an unregistered medicine into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits import of small quantities of a drug, whose import would otherwise be prohibited under Section 10 of the Drugs and Cosmetics Act 1940, for the exclusive personal use of a named patient. The mechanism is documented and accessible. Form 12A is the application for a permit to import a small quantity of a drug for personal use under the second proviso to Rule 36. Form 12B is the permit itself, issued by the office of the Drugs Controller General of India (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) showing the RMP's registration number and the quantity required for treatment. The quantity of any single drug imported shall not exceed one hundred average doses per application.

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 documentation is complete. In practice, families and hospitals plan for a two to four week window from physician decision to dispensed medicine because the bulk of elapsed time is upstream documentation assembly and downstream international logistics rather than the regulator's stamp. A complete application includes a clinical justification letter, the treating physician's National Medical Commission (NMC) registration number with state council registration where required, a patient identifier and supporting medical records, product details (brand name, generic name, manufacturer, strength, quantity), the dispensing facility's drug licence, and a chain-of-custody plan from the US manufacturer through to the dispensing pharmacy in India.

The cell-specific clinical-justification angle for Ubrelvy is the documentation of prior-line failure or triptan unsuitability. An Ubrelvy file rests on a documented migraine history: the diagnosis (ICD-10 G43 series), monthly migraine day count, prior abortives tried with their failure mode (lack of response, intolerable side effects, or cardiovascular contraindication to triptans), and the prescriber's stated reason for selecting ubrogepant over Nurtec ODT (rimegepant) or other oral options. The 8-dose-per-30-day FDA-labelled ceiling is referenced in the letter and aligns the requested pack size to a clinically reasonable monthly exposure. The 100-dose-per-application cap under Rule 36 maps comfortably onto one or two 10-tablet packs per filing.

Section 4. Where Ubrelvy gets dispensed in India

India's tertiary specialty network is unusually deep, and several institutions handle named-patient imports as established workflow. For Ubrelvy, the relevant capability is neurology and a hospital outpatient pharmacy able to dispense an oral medicine; the room-temperature handling profile means no specialised cold-chain pharmacy infrastructure is required. All India Institute of Medical Sciences (AIIMS), New Delhi has strong neurology and headache-clinic capability and routinely files compassionate and named-patient imports. Apollo Hospitals (Chennai flagship, Delhi, Bangalore, Hyderabad, Kolkata) operate dedicated international patient services, JCI and NABH accredited, with established neurology departments. Fortis Memorial Research Institute (Gurgaon), Mulund (Mumbai), Bangalore, and Kolkata sites carry headache and neurology services. Medanta - The Medicity (Gurgaon), Kokilaben Dhirubhai Ambani Hospital (Mumbai), Christian Medical College (CMC) Vellore, and Manipal Hospitals (Bangalore) similarly hold institutional drug licences and dispense imported neurology medicines.

For patients whose treating neurologist practices at a smaller hospital or a clinic without internal import infrastructure, the common pattern is to route through a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore that files the Rule 36 application on the prescribing physician's behalf. The importer handles customs at the port of entry (commonly Delhi, Mumbai, Bangalore, Chennai, or Hyderabad airports), takes receipt of the shipment under chain-of-custody documentation, and delivers the medicine to the prescribing hospital's outpatient pharmacy. The treating physician's clinical justification letter remains the cornerstone of the file regardless of who files it.

Section 5. Real cost picture for Ubrelvy in India

Costs sit in Indian rupees with the rupee floating against the US dollar. In May 2026 the USD/INR rate is in the 94 to 95 range. Reserve Meds quotes are itemised, not bundled.

- **Drug cost reference.** US wholesale acquisition cost for Ubrelvy is approximately USD 1,140 per 10-tablet pack of 50 mg or 100 mg as of January 2026, equivalent to roughly USD 114 per tablet at WAC. GoodRx and SingleCare retail cash reference prices in early 2026 ranged from approximately USD 1,086 to USD 1,464 per 10-tablet 100 mg pack. International cash-pay procurement for named-patient orders prices above US retail in line with NPP norms for branded specialty migraine therapy.
- **International logistics.** Ambient room-temperature shipping for an oral small molecule, USD 400 to 1,500 (approximately INR 38,000 to 142,000) depending on destination port and urgency window. No cold chain is required for ubrogepant.
- **Regulatory and concierge.** CDSCO Form 12B fees and customs handling are nominal relative to drug cost. India's Union Budget 2026-27 expanded the list of life-saving and rare-disease drugs eligible for customs duty exemption; ubrogepant is not on the listed exemption set, so standard customs duty and 12 percent GST apply unless the specific consignment qualifies under a separate exemption confirmed at documentation stage. Reserve Meds' concierge coordination fee is itemised separately on every firm quote.

India's private insurance market is large and segmented. Star Health and Allied Insurance, HDFC ERGO, ICICI Lombard, and Niva Bupa each handle named-patient imports case by case. None reimburses a Rule 36 personal import as a standard line item. CGHS provides for life-saving drugs not in the standard formulary to be considered by an Expert Committee under Special DG (DGHS); ESIC's formulary is narrower. Reserve Meds supplies the documentation that lets an insurer assess; the claim sits with you or your hospital. Cash-pay is the default posture.

Section 6. Typical timeline for Ubrelvy in India

The room-temperature handling profile makes Ubrelvy one of the lower-friction logistics cases in the Reserve Meds matrix. There is no cold-chain validation window and no temperature-loggers to reconcile at handoff. The end-to-end timeline tracks the documentation layer rather than the supply chain. CDSCO Form 12B issuance for routine cases with complete documentation is typically one to two days per CDSCO published guidance. US-side procurement through the open AbbVie wholesaler chain (McKesson, Cardinal Health, Cencora) runs in parallel during the documentation window. Once the permit is issued, ambient air freight under standard pharmaceutical-grade packaging clears Indian customs within 3 to 7 business days. Hospital

pharmacy or importer receipt, verification, and release to the treating physician completes the cycle. A reasonable end-to-end estimate from intake to first dose in hand is 2 to 4 weeks for a first import; refill cycles for a patient already established on the drug compress because the documentation reuses the original prescriber file. These ranges are typical, not promises.

Section 7. What your physician needs to provide

The clinical justification letter is the cornerstone of the Rule 36 application. For Ubrelvy, the letter should contain the patient identifier, the migraine diagnosis with ICD-10 coding, a documented monthly migraine day frequency and severity (typically MIDAS or HIT-6 score where available), a prior-therapy history naming the specific triptans and other abortives tried with their outcomes (lack of response, intolerable adverse effects such as chest tightness or paresthesias, or a clinical contraindication such as coronary artery disease, uncontrolled hypertension, prior ischemic stroke or TIA, or peripheral vascular disease), and the rationale for selecting ubrogepant specifically. Where the prescriber considered Nurtec ODT (rimegepant) or another gepant and selected ubrogepant, a one-sentence reason in the letter accelerates review.

Dosing in the letter aligns with the FDA-approved label: 50 mg or 100 mg orally at the onset of a migraine attack, with a second dose permitted at least 2 hours after the first if needed, a maximum of 200 mg in 24 hours, and a labelled ceiling of 8 doses per 30-day period. The letter should reference the prescriber's intended monthly exposure (one pack of 10 tablets typically covers a month for a patient with up to 8 migraine days, well inside the Rule 36 100-dose-per-application cap). Concomitant-medication review for strong CYP3A4 inhibitors (clarithromycin, itraconazole, ketoconazole, ritonavir-boosted regimens), where dose adjustment is required or co-administration is contraindicated, should be documented. Renal and hepatic function status is noted for patients where dose reduction applies. The prescribing physician's NMC registration number with state council registration completes the package, alongside the dispensing facility's drug licence number.

Section 8. Common questions about Ubrelvy in India

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover this? Each insurer assesses named-patient imports case by case. None reimburses a Rule 36 personal import as a standard line item. We do not promise coverage from any insurer. We supply the documentation that allows your insurer to assess; the claim itself sits with you or your hospital.

Will my CGHS or ESIC entitlement cover this? CGHS provides for life-saving and anti-cancer medicines not in the standard formulary to be considered by an Expert Committee under Special DG (DGHS) case-by-case. Drugs not approved by the DCGI face a stricter review. ESIC's formulary is narrower. Check eligibility with your CGHS Wellness Centre or ESIC dispensary before assuming coverage.

Will my NMC-registered physician's letter be sufficient? Yes. Any Registered Medical Practitioner with a valid NMC registration number can support a Form 12A application. Physicians at AIIMS, Tata Memorial, government medical colleges, and state tertiary hospitals routinely do so. Private-sector specialists at Apollo, Fortis, Medanta, Kokilaben, MGM, CMC Vellore, and Manipal also have signing authority subject to their institutional drug licence.

What is the safety profile? The most common adverse events in the ACHIEVE I and ACHIEVE II pivotal trials were nausea, somnolence, and dry mouth, each in single-digit percentages of patients. There were no serious treatment-related adverse events and no discontinuations for

adverse events in the pivotal trials. Ubrogepant does not produce the vasoconstriction associated with triptans, which is the defining cardiovascular safety advantage of the gepant class.

How is Ubrelvy different from Nurtec ODT? Both are oral gepants. Ubrelvy is FDA-approved for acute treatment only. Nurtec ODT carries a dual acute-plus-preventive indication on a single molecule. For a patient who needs only acute treatment, both are reasonable; for a patient who needs prevention alongside acute, the dual-indication Nurtec label may be more attractive. The selection is clinical and stays with your prescriber.

Does Ubrelvy interact with anti-CGRP injectable preventives? Co-administration with CGRP monoclonal antibodies used for prevention (erenumab, galcanezumab, fremanezumab, eptinezumab) is common practice and not contraindicated. Reserve Meds does not endorse specific regimens. The prescribing clinician makes the call.

Section 9. Where Reserve Meds fits in Ubrelvy cases

Reserve Meds is a US-based concierge coordinator. We do not replace your physician, do not replace the CDSCO, and do not replace your dispensing pharmacy or licensed importer. For Ubrelvy specifically, the orchestration we provide is a documentation kit your physician uses to assemble the Rule 36 application, US-side procurement through the open AbbVie wholesaler chain, ambient air-freight logistics under pharmaceutical-grade packaging, customs documentation aligned to the Form 12B permit, and a single named coordinator who stays with your case from intake through delivery. The single-coordinator model fits the common Indian family configuration where a grandmother in Hyderabad, an oncologist or neurologist in Mumbai, an adult child in Bangalore handling logistics, and a son in Dubai or London paying the invoice all need one chain of correspondence. No prior Reserve Meds case experience exists for Ubrelvy at the date of this page. Standard NPP coordination applies.

Section 10. Next step

If your neurologist has selected Ubrelvy for your migraine and you are based in India, the next step is the waitlist. We confirm eligibility within 24 to 48 hours and send a documentation kit to your physician. **Reserved for you.**

This guide is informational, not medical or legal advice. The Rule 36 framework requires a Registered Medical Practitioner's clinical judgment; Reserve Meds is the coordinator, not the prescriber.

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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