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

How patients in India legally obtain Nurtec ODT (rimegepant), the only oral migraine medicine FDA-approved for both acute and preventive use on a single label, 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 Nurtec ODT in India for adult patients with episodic migraine seeking the dual acute and preventive indication on a single oral molecule.

Section 1. Quick orientation

Nurtec ODT is the brand name for rimegepant, a small-molecule oral calcitonin gene-related peptide receptor antagonist in the gepant class, formulated as a 75 mg orally disintegrating tablet that dissolves on the tongue without water. The FDA approved Nurtec ODT for the acute treatment of migraine with or without aura in adults in February 2020 and expanded the label on May 27, 2021 to include the preventive treatment of episodic migraine in adults. With that second approval, Nurtec ODT became the first and currently the only oral migraine medication carrying both an acute and a preventive indication on a single label. Outside the United States, rimegepant is sold under the brand name Vydura. Neither brand is registered with the Central Drugs Standard Control Organization (CDSCO) for commercial sale in India. For adult patients in India whose treating neurologist has selected rimegepant, 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 Nurtec ODT 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, drugs registered for a different indication, and drugs not registered locally at all. Rimegepant falls in the third category. Pfizer, which acquired Biohaven Pharmaceutical in October 2022 and now holds the rimegepant franchise, has not filed Nurtec ODT or Vydura with the CDSCO. The drug is not stocked through Indian retail pharmacy chains or hospital formularies, and the dual-indication label that defines its clinical value is unavailable from any locally registered product.

The patient cohort reaching for Nurtec ODT through Rule 36 is specific. First, patients who have failed multiple oral preventives (topiramate, propranolol, amitriptyline) and need a different mechanism. Second, patients already on an injectable anti-CGRP monoclonal for prevention who experience breakthrough attacks and want a single oral molecule that covers both acute and preventive use on a single script. Third, patients who have responded to Nurtec ODT during US travel or treatment and need continuity of supply after returning home to India. The dual acute-plus-preventive indication on one molecule is the structural feature that distinguishes Nurtec ODT from every other approved migraine drug, and is the dominant driver of cross-border demand among Indian neurologists who have read the literature.

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

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. 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. 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 wholesaler through to the dispensing pharmacy in India.

The cell-specific clinical-justification angle for Nurtec ODT is the dual-indication rationale. A Nurtec ODT file is strongest when the prescriber's letter explicitly states which indication the patient is being treated for: acute treatment only, preventive treatment only, or both. For patients on the dual regimen, the letter should reference the FDA-labelled dosing: 75 mg every other day for prevention with a single 75 mg acute dose permitted on non-dosing days for breakthrough attacks, up to 18 doses per month total. The 18-dose monthly ceiling and the Rule 36 100-dose-per-application cap together set a clean documentation envelope: a four to five month supply maps within a single permit filing. Where the prescriber has selected rimegepant after multiple oral preventive failures, naming those prior agents in the letter accelerates CDSCO review.

Section 4. Where Nurtec ODT gets dispensed in India

India's tertiary specialty network has substantial neurology depth across both public and private institutions, any of which can support a Rule 36 dispensing chain for an oral migraine 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), Fortis Memorial Research Institute (Gurgaon) and Fortis network sites, Medanta - The Medicity (Gurgaon), Kokilaben

Dhirubhai Ambani Hospital (Mumbai), Christian Medical College (CMC) Vellore, Manipal Hospitals (Bangalore), and MGM Healthcare (Chennai) all 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 orally disintegrating tablet ships in foil-backed blister packs of 8 tablets per carton; the blister format satisfies tamper-evidence and child-resistance requirements at Indian customs without secondary packaging modification.

Section 5. Real cost picture for Nurtec ODT 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 Nurtec ODT per Pfizer's 2023 price disclosure is USD 951.45 per carton of 8 tablets (75 mg), pricing a single acute dose at approximately USD 119. For preventive use at 75 mg every other day, monthly consumption is approximately 15 tablets, or roughly two cartons. Retail and uninsured US pricing in 2026 ranges from approximately USD 1,050 to USD 1,290 per 8-tablet pack across major pharmacy chains. International cash-pay procurement for named-patient orders prices above US retail in line with NPP norms.
- **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 rimegepant.
- **Regulatory and concierge.** CDSCO Form 12B fees and customs handling are nominal relative to drug cost. Standard customs duty and 12 percent GST apply unless the consignment qualifies under a specific 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 Nurtec ODT in India

The room-temperature handling profile makes Nurtec ODT 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 Pfizer 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 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 Nurtec ODT, 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), the specific indication being treated (acute, preventive, or both), and a prior-therapy history. For patients on the preventive indication, the letter should name the oral preventives previously tried (topiramate, propranolol, amitriptyline, candesartan) and any injectable anti-CGRP monoclonals (erenumab, galcanezumab, fremanezumab, eptinezumab) tried with their outcomes. For patients on the acute indication, the letter should name the abortives previously tried (triptans, NSAIDs, antiemetics) and any cardiovascular contraindications to triptan use. The rationale for selecting rimegepant specifically should be stated, including the dual-indication advantage where the patient needs both acute and preventive coverage.

Dosing in the letter aligns with the FDA-approved label. Acute: 75 mg taken orally as a single dose at the onset of a migraine attack, allowed to dissolve on or under the tongue, no water required, maximum 75 mg in 24 hours; safety beyond 15 acute treatments per 30-day period has not been established. Preventive: 75 mg taken orally every other day, with a single 75 mg acute dose permitted on a non-dosing day for breakthrough attacks, not exceeding 18 doses per month total. Strong CYP3A4 inhibitors (clarithromycin, ketoconazole, itraconazole) should be flagged and avoided. Strong and moderate CYP3A4 inducers (rifampin, phenytoin, carbamazepine, St. John's wort) reduce rimegepant exposure and should be avoided. Patients with severe hepatic impairment (Child-Pugh C) should not use rimegepant. 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 Nurtec ODT 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.

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) 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, Apollo, Fortis, Medanta, Kokilaben, MGM, CMC Vellore, and Manipal routinely sign these letters as part of established institutional workflow.

What is the safety profile? The most common adverse reactions in clinical trials were nausea (2 percent acute, 3 percent preventive) and hypersensitivity reactions including dyspnea and rash. The drug carries no boxed warning. Hepatotoxicity signals seen with earlier-generation gepants such as telcagepant have not been observed with rimegepant in pivotal trials or post-marketing data through 2026.

How is Nurtec ODT different from Ubrelvy? Both are oral gepants. Ubrelvy (ubrogepant) 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 is the structural reason for selection. The selection is clinical and stays with your prescriber.

Can Nurtec ODT be combined with an injectable anti-CGRP monoclonal? Co-administration with erenumab, galcanezumab, fremanezumab, or 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 Nurtec ODT 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 Nurtec ODT specifically, the orchestration we provide is a documentation kit your physician uses to assemble the Rule 36 application, US-side procurement through the open Pfizer 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 room-temperature handling profile and the orally disintegrating tablet format make Nurtec ODT one of the most logistics-friendly molecules on the matrix, suitable for consolidation with other small-molecule shipments in a single air-freight movement where the family has additional cross-border medicine needs. No prior Reserve Meds case experience exists for Nurtec ODT at the date of this page. Standard NPP coordination applies.

Section 10. Next step

If your neurologist has selected Nurtec ODT 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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