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

How patients in India obtain Aimovig (erenumab-aooe) for migraine prevention through the CDSCO Rule 36 personal-import permit on Form 12A and Form 12B, in a market where CGRP monoclonal antibody access remains limited.

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

Quick orientation

Aimovig is the Amgen and Novartis co-developed monoclonal antibody approved by the US FDA in May 2018 for the preventive treatment of migraine in adults. It was the first CGRP-pathway monoclonal antibody to reach the US market and the first FDA-approved antibody therapeutic against any G-protein-coupled receptor. Aimovig is the only CGRP-receptor antibody (the other three class members bind the CGRP ligand). Erenumab is not broadly registered with CDSCO at the standard commercial level in India, and Indian patients typically access Aimovig through Rule 36 named-patient import on the basis of a treating neurologist's prescription. CGRP monoclonal antibody access in India is limited overall, and the named-patient route is the practical channel for patients whose treating physician has decided Aimovig is the right preventive option. Reserve Meds operates as a legitimate cross-border named-patient channel under the CDSCO framework.

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Why patients in India reach for Aimovig through NPP

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. For US originator specialty biologics like Aimovig, three patterns of access gap recur. A drug can be registered with CDSCO but the specific brand, strength, or pack size is not stocked in the dispensing pharmacy on the day therapy is meant to start. A drug can be registered for one indication and prescribed for another FDA-approved use that is not on the Indian label. A drug can be FDA-approved in the United States but not registered locally at all. For Aimovig the pattern is closer to the third: erenumab is not broadly registered with CDSCO at the commercial level, and access for Indian patients runs through Rule 36 personal import.

The CGRP monoclonal antibody class as a whole has limited access in India, which sharpens the named-patient case. Indian neurology practice still positions older oral preventives (topiramate, propranolol, amitriptyline, candesartan, flunarizine) as first-line for migraine prevention, with class members of the CGRP monoclonal antibody class (Aimovig, Ajovy, Emgality, Vyepti) reserved for patients who have failed multiple oral preventives. Where private insurance does cover migraine therapy in India it typically denies CGRP biologics on cost grounds, requiring documented failure of multiple older preventives before any CGRP access is authorised. Patients who have already failed those oral preventives and have the capacity to pay out of pocket route through the named-patient pathway rather than wait through appeal cycles. Within the CGRP class, neurologists trained in the US or Europe often prefer to keep a patient on the specific class

member that produced a response in earlier treatment history; if that product is Aimovig and the locally available alternative is a different CGRP antibody, the family chooses to import rather than switch class members. Reserve Meds frames Aimovig cases as a documented cross-border channel under the CDSCO Rule 36 framework.

The CDSCO named-patient pathway for Aimovig

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 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 the permit. 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 NMC registration number and the quantity required for treatment. The quantity of any single drug imported shall not exceed one hundred average doses per application, which for monthly Aimovig comfortably covers an annual supply.

For Aimovig the clinical-justification angle is documented failure of older oral preventives plus migraine-day burden documentation. A complete CDSCO application typically includes:

- A clinical justification letter naming the diagnosis (episodic or chronic migraine per ICHD-3 criteria, with monthly migraine day count documented), the prior oral-preventive failure history (drug, dose, duration, intolerance documentation), the current monthly migraine days and headache days, the patient's MIDAS or HIT-6 score, and the documented reason a CGRP-receptor antibody specifically is required
- The treating physician's NMC registration number and a copy of state council registration where required
- A patient identifier and supporting medical records, including the headache diary
- Product details: Aimovig (erenumab-aooe) 70 mg/mL or 140 mg/mL single-dose SureClick autoinjector or prefilled syringe, manufacturer Amgen Inc., quantity (not to exceed one hundred average doses per application; for monthly dosing this covers approximately 8 years of therapy in a single filing, though families typically file for a 12-month supply at a time)
- The dispensing facility's drug licence (hospital pharmacy or specialty importer's wholesale licence) with cold-chain receiving capability
- A chain-of-custody plan from the US specialty-pharmacy source to the dispensing pharmacy in India, including continuous 2-to-8-degree cold-chain documentation with the 7-day room-temperature excursion budget noted

CDSCO's published guidance states the Form 12B permit issues on a priority basis, typically within one to two days for routine applications where the documentation is complete. In practice families plan for a two to four week window from physician decision to dispensed medicine.

Where Aimovig gets dispensed in India

Aimovig is a refrigerated biologic delivered by patient self-administered subcutaneous injection. The dispensing footprint is the neurology pharmacy desks at tertiary specialty institutions, plus

CDSCO-licensed specialty importers with validated cold-chain receiving infrastructure. The product does not require infusion-suite capability; once the patient receives the autoinjector under chain-of-custody at 2 to 8 degrees Celsius, they can self-inject at home after a brief device-handling demonstration. Institutions that file named-patient imports as established practice include the All India Institute of Medical Sciences (AIIMS) in New Delhi, Apollo Hospitals (Chennai flagship, with Delhi, Bangalore, Hyderabad, and Kolkata), Fortis Memorial Research Institute in Gurgaon and the Fortis Mulund, Bangalore, and Kolkata sites, Medanta in Gurgaon, Kokilaben Dhirubhai Ambani Hospital in Mumbai, MGM Healthcare in Chennai, Christian Medical College (CMC) in Vellore, and Manipal Hospitals in Bangalore.

For migraine cases the natural homes are the headache and general neurology services at AIIMS Delhi, Apollo Chennai, Apollo Delhi, Medanta Gurgaon, CMC Vellore, and Manipal Bangalore. Families in tier 2 cities typically route to one of these centres for the prescription and clinical justification letter, then work with a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore that files the Form 12A and handles the cold-chain documentation. The product's 7-day room-temperature excursion budget provides operational flexibility for last-mile transit in hot-climate corridors, though it does not relax the underlying cold-chain requirement.

Real cost picture for Aimovig in India

US wholesale acquisition cost for Aimovig is approximately USD 767 per single-dose autoinjector at the 70 mg/mL or 140 mg/mL strength, per Amgen's 2025 published list pricing. Patient list pricing is published as approximately USD 575 per monthly injection on the manufacturer's patient-facing pricing page, with the annual list price stated as approximately USD 6,900 for monthly dosing. These figures are list, not net. The order-of-magnitude reference for US-sourced NPP Aimovig is therefore approximately USD 6,900 to USD 9,200 per year at US list (depending on whether the patient is on the 70 mg or 140 mg monthly dose), before specialty pharmacy markup, cold-chain logistics, customs handling, and the Reserve Meds coordination fee.

The Indian rupee floats against the US dollar. In May 2026 the USD/INR rate sits in the 94 to 95 range. Annual Aimovig at US WAC translates to roughly INR 6.5 lakh to INR 8.7 lakh per year at the prevailing rate, with international cold-chain logistics adding USD 400 to USD 1,200 per shipment (approximately INR 38,000 to INR 1.1 lakh). Families typically file for a 3-month or 6-month supply at a time to balance customs handling against cold-chain refresh cadence. India's Union Budget 2026-27 expanded the list of life-saving drugs eligible for customs duty exemption, and the specific HSN code and exemption status are confirmed at the documentation stage. GST on most life-saving medicines is 5%.

On the insurance side, Star Health, HDFC ERGO, ICICI Lombard, and Niva Bupa each handle named-patient imports case by case. None reimburse a Rule 36 personal import as a standard line item; some plans cover migraine therapy under specific riders but typically require documented failure of multiple oral preventives before authorising any CGRP class member. CGHS coverage flows through the Special DG (DGHS) Expert Committee, with stricter constraints on products not approved by the DCGI. Cash-pay is the default posture.

Typical timeline for Aimovig in India

For an established Aimovig candidate with a clean neurology letter, documented oral-preventive failure history, and a tertiary-centre prescription, the typical end-to-end cycle from first inquiry to first injection is 2 to 4 weeks. CDSCO published guidance puts the Form 12B priority window at 1 to 2 days for complete routine documentation. US-side sourcing through Amgen specialty-

pharmacy partners adds 1 to 2 weeks. International cold-chain transit and Indian customs clearance under the import permit at Delhi, Mumbai, Bangalore, Chennai, or Hyderabad airport adds 3 to 7 days, with continuous temperature monitoring at 2 to 8 degrees Celsius across the customs handoff. Cold-chain biologic shipments add 2 to 3 days versus ambient products. The product's 7-day room-temperature excursion budget reduces the operational risk of customs holds during hot-climate transit. Once the first injection is delivered, monthly self-administration continues at home. Timelines are presented as typical ranges and not as promises; specific dates are confirmed at firm-quote issuance.

What your physician needs to provide

The clinical justification letter for Aimovig is the centrepiece of the CDSCO package. For this product the letter typically includes:

- The patient's confirmed diagnosis: episodic migraine (fewer than 15 headache days per month) or chronic migraine (15 or more headache days per month with at least 8 having migraine features), per ICHD-3 criteria, with monthly migraine day count documented from a headache diary
- Disability burden at baseline: MIDAS or HIT-6 score, work and family impact documentation
- Prior preventive therapy history: at least two and ideally three oral preventives from different classes (topiramate, propranolol or another beta-blocker, amitriptyline, candesartan, flunarizine, or sodium valproate), with documented dose, duration, response, and intolerance or contraindication for each
- Acute therapy use: triptan use, NSAID use, and any concern for medication-overuse headache
- The dosing plan: 70 mg subcutaneously once monthly as starting dose, with titration to 140 mg once monthly (administered as a single 140 mg autoinjector or as two 70 mg injections given consecutively) for patients who may benefit from a higher dose; no loading dose; no taper; therapy reassessed at 3 months for episodic migraine and 3 to 6 months for chronic migraine
- The patient self-administration plan and site rotation guidance (abdomen, thigh, upper arm), with the 30-minute warm-up from refrigerator before injection
- The monitoring plan: blood pressure before initiation and during therapy, particularly after the first dose (2024 FDA label addition for hypertension); patient education on new or worsening constipation, Raynaud's symptoms (cold-induced colour change in fingers or toes), and hypersensitivity symptoms
- The PvPI adverse-event reporting plan as part of the Pharmacovigilance Programme of India obligation

The treating physician's NMC registration number must appear on the prescription. State-council registration is required for practice in a particular state.

Common questions about Aimovig in India

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover Aimovig? Each plan handles named-patient imports case by case. None of the major private insurers reimburse a

Rule 36 personal import as a standard line item. Some plans cover migraine therapy under specific riders but typically require documented failure of multiple oral preventives before authorising any CGRP class member. Reserve Meds supplies the documentation set that lets the insurer assess the case. Cash-pay is the default posture.

Will CGHS or ESIC cover Aimovig? 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, with stricter constraints on drugs not approved by the DCGI. Migraine prevention is typically not categorised as life-saving therapy. ESIC's formulary is narrower and not structured for routine personal-import reimbursement.

Why Aimovig versus Ajovy, Emgality, or Vyepti? Aimovig is the only CGRP-receptor antibody; the other three bind the CGRP ligand. Choice within the CGRP class is typically driven by prior treatment response, route preference (subcutaneous monthly versus IV quarterly), constipation risk profile, and local availability. There is no head-to-head trial that establishes one CGRP monoclonal antibody as clinically superior. Patients who responded to Aimovig in a prior course often prefer to continue on Aimovig rather than switch. Reserve Meds supports whichever CGRP class member the treating neurologist prescribes.

What about oral CGRP options (gepants)? Nurtec ODT (rimegepant) and Qulipta (atogepant) are oral CGRP receptor antagonists approved for migraine prevention and are an alternative to the monoclonal antibody class. They are also reached through Reserve Meds named-patient coordination in India, with somewhat simpler ambient logistics. The choice between an injectable CGRP antibody and an oral gepant is a clinician-led discussion.

What is the safety profile? The most common adverse reactions in clinical trials were injection site reactions and constipation. The FDA label was updated in August 2024 to add warnings for hypertension (new-onset or worsening of pre-existing hypertension, most commonly reported within 7 days of the first dose) and Raynaud's phenomenon. Hypersensitivity reactions, including rash and angioedema, have also been reported. Blood pressure monitoring before initiation and during therapy is important, particularly after the first dose. Patients with constipation-prone gastrointestinal histories should discuss this risk with their physician before starting.

How is the cold chain managed across long Indian transit? Aimovig's label permits a single excursion of up to 7 days at room temperature up to 25 degrees Celsius. Reserve Meds routes shipments through 3PL partners with validated cold-chain packout and continuous temperature monitoring, and the 7-day excursion budget provides operational buffer for customs holds and last-mile transit in hot-climate corridors.

Where Reserve Meds fits in Aimovig cases

Reserve Meds is a US-based concierge coordinator. We do not replace your neurologist, do not replace CDSCO, and do not replace the dispensing pharmacy or the licensed importer. For Aimovig specifically we orchestrate the US-side sourcing through Amgen specialty-pharmacy partners, the regulatory documentation kit your physician needs for Form 12A (oral-preventive failure documentation template, monthly migraine day reference, dosing reference by patient response, blood-pressure monitoring plan, the August 2024 label updates for hypertension and Raynaud's, PvPI reporting reference), validated cold-chain international logistics under chain-of-custody at 2 to 8 degrees Celsius with the 7-day excursion budget, and a single named coordinator who carries the patient through documentation, initial delivery, and monthly continuity. Documented failure of at least two oral preventives is the standard intake artefact. We

do not coordinate off-label use, and we will decline intake for prescriptions outside the FDA-approved migraine prevention indication.

Next step

If your neurologist has decided Aimovig is the right next step for migraine prevention and the CGRP monoclonal antibody class access is the bottleneck, the Rule 36 personal-import pathway through CDSCO is the route. Join the waitlist below and we will confirm eligibility within 24 to 48 hours and route the documentation kit to your physician.

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