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

How adult and pediatric patients in India with KMT2A-rearranged or NPM1-mutated relapsed or refractory acute leukemia legally obtain Revuforj (revumenib) from US-source supply through CDSCO personal importation, with molecular confirmation and differentiation-syndrome surveillance built into the case plan.

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Quick orientation

Revuforj (revumenib) is a first-in-class oral small-molecule menin inhibitor approved by the US FDA on 15 November 2024 for the treatment of relapsed or refractory acute leukemia with a KMT2A translocation in adult and pediatric patients one year of age and older. In October 2025 the FDA expanded the label to include relapsed or refractory acute myeloid leukemia with a susceptible NPM1 mutation in patients one year of age and older. It is administered orally as a film-coated tablet twice daily. Revuforj is approved by the FDA only as of this review; there is no CDSCO registration in India. Indian hematology centres reach the medicine through the Central Drugs Standard Control Organization (CDSCO) personal importation framework under Rule 36 of the Drugs and Cosmetics Rules 1945, with Form 12A application and Form 12B permit issued by the Drugs Controller General of India (DCGI), or through the Compassionate Use route for AIIMS New Delhi, Tata Memorial Centre Mumbai, and other government tertiary hospitals. Reserve Meds coordinates the US-side SyndAccess-authorized specialty pharmacy sourcing under DSCSA serialization, ambient international logistics, and the documentation kit your hematologist or pediatric oncologist needs to file.

Reserved for you.

Why patients in India need Revuforj via the named-patient pathway

India has a deep hematology and stem-cell-transplant network. Tata Memorial Centre Mumbai's bone marrow transplant unit is among the highest-volume in South Asia. Christian Medical College (CMC) Vellore has been globally recognised for hematology for decades. AIIMS New Delhi handles adult and pediatric acute leukemia under both routine and Compassionate Use frameworks. Apollo, Fortis, Medanta, Kokilaben, MGM, and Manipal run active BMT programmes with hematology subspecialty services. What is missing for relapsed or refractory KMT2Ar or NPM1-mutated acute leukemia patients is a routinely stocked menin inhibitor. Revuforj is single-source globally with no generic, no therapeutically equivalent local substitute, and no CDSCO registration. The Rule 36 framework is the legal route.

Three features make Revuforj an unusually clean named-patient case profile for Indian patients. First, KMT2A-rearranged acute leukemia is rare. It accounts for a small minority of adult AML and a slightly larger fraction of infant and pediatric ALL, which discourages local stocking. Second, Revuforj is first-in-class with no approved competitor in the menin-inhibitor class. Third, the pediatric eligibility (age one year and older at first FDA approval) is unusual for a novel targeted oncology therapy. Many novel oncology approvals are adult-only at launch with pediatric extension years later. Revuforj's pediatric label at first approval means infant and pediatric KMT2Ar leukemia cases (a population with historically poor outcomes) reach it on the same regulatory basis as adults. Pediatric hematology referrals out of India to CMC Vellore, Tata Memorial Mumbai, and AIIMS New Delhi from across South Asia make Revuforj a high-fit candidate.

The October 2025 label expansion to relapsed or refractory acute myeloid leukemia with a susceptible NPM1 mutation in patients one year of age and older broadened the eligible Indian population. NPM1 is the single most common recurrent mutation in adult AML, present in roughly a quarter to a third of de novo AML cases at first molecular diagnosis. Many of those patients respond to initial intensive chemotherapy, but the relapsed and refractory NPM1-mutated subset has

historically had limited targeted options. Revuforj's label-confirmed activity in this molecular subset, combined with its oral once-twice-daily continuous dosing schedule and the absence of cold-chain logistics, makes it an unusually practical add to the Indian hematology toolkit when sourced through the Rule 36 framework.

The CDSCO Rule 36 named-patient pathway for Revuforj

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 the import of a small quantity 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 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 National Medical Commission (NMC) registration number and the quantity required for treatment. The quantity of any single drug imported is capped at one hundred average doses per application, which for Revuforj's continuous twice-daily oral dosing covers approximately seven weeks of supply per filing for an adult on the 270 mg twice-daily regimen.

For institutional Compassionate Use, the parallel pathway is the Compassionate Use application route to the DCGI by a government hospital, a registered medical practitioner, a pharmaceutical company, or the patient. This route applies when the drug is approved by a recognised reference authority for a life-threatening condition. Relapsed or refractory acute leukemia, particularly in pediatric patients, fits the life-threatening framing precisely. AIIMS, Tata Memorial, and CMC Vellore have established Compassionate Use workflow.

For Revuforj specifically, the clinical-justification angle is precise and hinges on molecular confirmation. The strongest Form 12A applications consistently document: a hematologist's or pediatric oncologist's confirmed diagnosis of relapsed or refractory acute leukemia with KMT2A translocation (KMT2Ar, historically described as MLL-rearranged) confirmed by FISH or cytogenetics, or NPM1 mutation confirmed by molecular testing (for the AML subset added to the label in October 2025); documentation of the prior lines of therapy with dates, response, and reason for relapse or refractoriness; patient age and weight (because dosing is weight-based and pediatric eligibility starts at one year); the proposed dosing plan following the FDA-labeled regimen with explicit attention to whether the patient is on a strong CYP3A4 inhibitor such as posaconazole or voriconazole (clinically common in this population for invasive fungal prophylaxis, requiring dose reduction); and the planned monitoring plan for differentiation syndrome surveillance during the first 28 days, QT-interval prolongation, and myelosuppression. CDSCO's published guidance states Form 12B is typically issued within one to two business days for routine applications where documentation is complete.

Where Revuforj gets dispensed in India

Revuforj is a solid oral dosage form with room-temperature stability and no cold chain. This is operationally favorable: international logistics are materially simpler than for biologics and cell therapies that dominate the oncology NPP request mix. There is no temperature excursion risk in transit and no compounding step at the destination. The dispensing ins