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

How adults in India with chronic refractory gout legally obtain Krystexxa (pegloticase) from US-source supply through CDSCO personal importation, with mandatory G6PD-deficiency screening and infusion-center readiness built into the case plan.

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

Quick orientation

Krystexxa (pegloticase) is a pegylated recombinant uricase enzyme administered as an intravenous infusion every two weeks. It catalyzes the conversion of uric acid to allantoin, bypassing the metabolic bottleneck that drives hyperuricemia in patients whose oral urate-lowering therapy has failed. The US FDA first approved Krystexxa on 14 September 2010 for chronic gout in adult patients refractory to conventional therapy. On 7 July 2022 the FDA approved a supplemental BLA expanding the labeling to include co-administration with methotrexate, supported by the MIRROR RCT trial. The European Marketing Authorisation was withdrawn at the marketing-authorisation holder's request in June 2016 on commercial grounds, and Krystexxa is not registered in India through CDSCO. Indian patients with chronic refractory tophaceous gout reach Krystexxa 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). Reserve Meds coordinates US-side specialty distributor sourcing under DSCSA serialization, validated 2 to 8 degree Celsius cold-chain logistics, and the documentation kit your rheumatologist needs to file, with G6PD-deficiency screening confirmation upstream of any procurement step.

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

India has a sizeable population with chronic tophaceous gout that has failed conventional urate-lowering therapy. Allopurinol at maximum tolerated dose and febuxostat are widely used and widely effective, but a clinically meaningful subset of patients continue to have tophi that grow, joints that erode, and quality of life that deteriorates despite years of oral therapy. For these refractory patients, pegloticase is uniquely effective at rapidly lowering serum uric acid to levels that mobilize and dissolve monosodium urate deposits. The clinical population is small but the unmet need is intense.

What India lacks is local registration. Krystexxa is not on the CDSCO register, was withdrawn from the EU register in 2016 on commercial grounds, is not registered in Japan via PMDA, and is not registered through Health Canada as a commercially marketed product. There is no other commercially approved uricase product in the United States or in India at the same indication. The narrow biologic mechanism, the cold-chain shipping requirement, the IV infusion administration, and the absence of commercial registration outside the United States together place the case profile clearly inside the named-patient lane rather than any commercial import channel. The Rule 36 framework is the legal route. Rheumatology specialists at AIIMS, Apollo, Fortis, Medanta, Kokilaben, MGM, CMC Vellore, and Manipal handle the case workup, and CDSCO-licensed specialty importers in Mumbai, Delhi, and Bangalore manage the filing and chain-of-custody documentation.

The CDSCO Rule 36 named-patient pathway for Krystexxa

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.

For Krystexxa specifically, the clinical-justification angle hinges on three elements that the CDSCO reviewer looks for in a refractory-disease biologic: a rheumatologist's confirmed diagnosis of chronic gout refractory to conventional therapy, defined per the FDA label as an adult who has failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose, or for whom those agents (allopurinol, febuxostat) are contraindicated; mandatory documented G6PD (glucose-6-phosphate dehydrogenase) deficiency screening with a negative result, because Krystexxa is contraindicated in patients with G6PD deficiency due to the risk of life-threatening hemolytic reactions and methemoglobinemia (the label specifically flags patients of African, Mediterranean including Southern European and Middle Eastern, and Southern Asian ancestry as at increased risk, and this is a critical issue for the Indian population); and the proposed dosing plan following the FDA-labeled regimen of 8 mg every two weeks IV with premedication and recommended co-administration of oral methotrexate 15 mg weekly plus folic acid 1 mg daily per the 2022 label update. The dispensing infusion centre's drug licence, the chain-of-custody plan, and the patient identifier complete the file.

CDSCO's published guidance states Form 12B is typically issued within one to two business days for routine applications where documentation is complete. Indian families and rheumatology centres plan for a two to four week window from rheumatologist decision to first infusion, with the elapsed time dominated by upstream documentation assembly (especially G6PD screening if not already on file) and downstream cold-chain logistics rather than the regulator's stamp.

Where Krystexxa gets dispensed in India

Krystexxa is administered only in supervised settings capable of managing anaphylaxis, which in practice means hospital infusion centres, rheumatology infusion suites, and qualified specialty infusion centres. The dispensing institution must have refrigerated 2 to 8 degree Celsius storage in the original carton, aseptic-compounding capacity for diluting Krystexxa into 250 mL of 0.9 percent or 0.45 percent sodium chloride for the IV bag, IV access, anaphylaxis-management drugs and trained staff, and the 120-minute-minimum infusion suite time per dose.

The Indian institutions with rheumatology programmes and the infusion-suite infrastructure to support a Rule 36 import of Krystexxa include AIIMS New Delhi (apex public-sector institution with established rheumatology), Apollo Hospitals (Chennai flagship, Delhi, Bangalore, Hyderabad, with rheumatology services and infusion suites), Fortis Healthcare (Fortis Memorial Research Institute Gurgaon and Mulund Mumbai), Medanta The Medicity Gurgaon, Kokilaben Dhirubhai Ambani Hospital Mumbai, MGM Healthcare Chennai, Christian Medical College (CMC) Vellore, and Manipal Hospitals Bangalore. For patients in smaller cities without a rheumatology infusion suite, the practical pattern is to route the case to one of the centres above for at least the first several infusions, or to work through a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore that handles the Form 12A filing for a patient receiving therapy at a local rheumatology infusion centre with documented anaphylaxis-readiness.

Real cost picture for Krystexxa 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. Public WAC data points indicate that Krystexxa's per-vial price has risen substantially since US launch. Recent regulatory and pricing references cite an annual WAC of approximately USD 650,000 for the standard every-two-week regimen, which implies a current per-infusion WAC in the range of USD 25,000 per vial. Exact current per-vial WAC

figures sit behind paywalled pricing databases and the per-vial estimate should be confirmed at the time of any patient-specific quote. At the prevailing USD/INR rate, the annualised US drug cost converts to a substantial INR 6 crore-plus per year range, before India-side logistics, hospital infusion fees, premedication, and the methotrexate co-administration regimen.

International validated 2 to 8 degree Celsius cold-chain shipping for the biweekly dosing cadence typically runs USD 400 to 900 per shipment depending on city of destination and whether multiple infusions are consolidated. CDSCO permit fees are nominal. India's Union Budget 2026-27 expanded customs-duty exemption on a set of named life-saving and rare-disease drugs; the specific HSN code and exemption status of each Krystexxa shipment is confirmed at the documentation stage. GST on most life-saving medicines is 5 percent. The dispensing hospital's infusion fees, the premedication regimen (antihistamines, acetaminophen, IV corticosteroid such as methylprednisolone 125 mg or equivalent), the oral methotrexate plus folic acid co-administration, and any management of infusion reactions sit on the hospital's side of the ledger. Reserve Meds itemises the US-side procurement, the international cold-chain logistics, and the concierge coordination fee separately on every firm quote.

None of the major Indian private insurers (Star Health and Allied Insurance, HDFC ERGO, ICICI Lombard, Apollo Munich, Niva Bupa) reimburse a Rule 36 personal import of an unregistered refractory-gout biologic as a standard line item. The chronic refractory tophaceous gout indication does not fit standard insurer-formulary categories and cash-pay is the operating default. CGHS provides for life-saving medicines that are 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 DCGI.

Typical timeline for Krystexxa in India

For a routine Indian Krystexxa case, the CDSCO Form 12B permit window is typically one to two business days from a complete Form 12A filing. The cold-chain biologic class adds two to three days to international transit windows compared with ambient products. Validated 2 to 8 degree Celsius shipping is rated for 72 to 120 hours, dictating route selection and customs-clearance timing at Delhi, Mumbai, Bengaluru, Chennai, or Hyderabad airports. Upstream documentation assembly typically includes the G6PD-deficiency screening turnaround time at the local laboratory, which adds three to seven days where the test is not already on file. End-to-end, most patients plan for two to four weeks from rheumatologist decision to first infusion, with the elapsed time dominated by upstream G6PD screening and Form 12A assembly rather than the permit stamp. Because Krystexxa is dosed every two weeks for as long as response is maintained, Reserve Meds plans repeat-shipment cadence at case acceptance.

What your physician needs to provide

The clinical justification letter is the cornerstone of the Form 12A filing. For Krystexxa, the strongest letters consistently include: a rheumatologist's confirmed diagnosis of chronic gout refractory to conventional therapy, with serum uric acid history, tophus burden, and any imaging documenting joint erosion or tophaceous deposits; documentation of prior xanthine oxidase inhibitor therapy at maximum tolerated dose (allopurinol, febuxostat) with failure to normalize sUA and inadequately controlled signs and symptoms, or contraindication documented; mandatory G6PD-deficiency screening result attached, with the negative result explicitly noted and the patient's ancestral background acknowledged; the proposed dosing plan (8 mg IV every two weeks, infused over no less than 120 minutes, with the premedication regimen including antihistamine and corticosteroid documented); the co-administration plan with oral methotrexate 15 mg weekly plus folic acid 1 mg daily per the 2022 label update, or the rationale for monotherapy if methotrexate is contraindicated; the pre-infusion serum uric acid monitoring plan with discontinuation criteria when sUA rises above 6 mg/dL on two consecutive measurements; and the prescribing physician's NMC registration number. The dispensing infusion centre's drug licence, the chain-of-custody plan from the US specialty distributor to the Indian rheumatology infusion centre, and the patient identifier complete the file.

The treating rheumatologist retains the clinical decision and the Pharmacovigilance Programme of India (PvPI) adverse-event reporting obligation. Reserve Meds will not coordinate a Krystexxa shipment without documented G6PD-deficiency screening with a negative result.

Common questions about Krystexxa in India

Why is G6PD screening so important in India?

Krystexxa is contraindicated in patients with G6PD deficiency because of the risk of life-threatening hemolytic reactions and methemoglobinemia. The FDA label specifically flags patients of African, Mediterranean (including Southern European and Middle Eastern), and Southern Asian ancestry as at increased risk for G6PD deficiency. This is a critical issue for the Indian population. Screening before initiation is mandatory and non-negotiable. Reserve Meds confirms a documented negative G6PD result at intake and will not proceed without it.

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover Krystexxa?

Each plan handles named-patient imports case by case. None of the major Indian private insurers reimburse a Rule 36 personal import of an unregistered specialty biologic for refractory gout as a standard line item. Reserve Meds provides the itemised documentation that lets the insurer evaluate. Cash-pay is the operating default.

What is the safety profile beyond G6PD?

The Krystexxa label carries a boxed warning for anaphylaxis and infusion reactions, in addition to G6PD-deficiency-associated hemolysis and methemoglobinemia. Anaphylaxis was reported in approximately 6.5 percent of patients on the every-two-week regimen in pre-marketing trials. Patients must be premedicated with antihistamines and corticosteroids and monitored for an appropriate period after each infusion. Co-administration with methotrexate per the 2022 MIRROR-based label update reduces infusion reaction frequency substantially (4 percent on the co-administration arm versus 31 percent on pegloticase alone).

What is the monitoring requirement during therapy?

Serum uric acid should be measured before each infusion. A rising pre-infusion sUA, particularly above 6 mg/dL on two consecutive measurements, signals loss of response driven by anti-PEG antibody formation. The label recommends discontinuing Krystexxa when sUA rises above 6 mg/dL on two consecutive measurements before the next infusion, because continued dosing in that setting increases the risk of infusion reactions and anaphylaxis. The methotrexate co-administration regimen extends durable response considerably.

Is there a competitor or alternative?

Within the urate-lowering class, oral xanthine oxidase inhibitors (allopurinol, febuxostat) are first-line. Probenecid is a uricosuric option in some patients. By definition, Krystexxa is reserved for patients who have already failed those options. There is no other commercially approved uricase product in the United States at the same indication, and none in India.

What is the typical course duration?

There is no fixed end point. Treatment continues every two weeks as long as serum uric acid remains controlled. Many patients on pegloticase monotherapy discontinue within 6 to 12 months because of anti-PEG antibody formation. The methotrexate co-administration regimen extends durable response. Planning for a multi-month course on the methotrexate co-administration regimen is the working assumption, with the option to discontinue triggered by rising sUA.

Where Reserve Meds fits in Krystexxa cases

Reserve Meds is a US-based concierge coordinator. We do not replace your rheumatologist, do not replace CDSCO or the DCGI, and do not replace the dispensing rheumatology infusion centre or the licensed specialty importer. What we do is orchestrate the US-side specialty distributor sourcing under DSCSA serialization with full pedigree, validated 2 to 8 degree Celsius cold-chain logistics with temperature monitoring through to handoff, and the documentation kit your rheumatologist

needs for the Form 12A filing. No prior Reserve Meds case experience exists for Krystexxa in India as of this review, so standard NPP coordination applies with particular drug-specific attention to four operational realities: documented G6PD-deficiency screening with a negative result before any procurement step; cold-chain integrity across multi-leg international transit; a receiving infusion centre with anaphylaxis-management capacity (IV access, resuscitation drugs, trained staff); and pricing quoted per-vial after live source verification at the time of inquiry given the WAC trajectory. A single named coordinator carries the case from intake through the every-two-week dose cycle and the methotrexate co-administration management period.

Next step

If an Indian adult with chronic refractory tophaceous gout has a rheumatologist considering Krystexxa, add the case to the waitlist. We will respond within 24 to 48 hours with a documentation kit for your rheumatologist that includes the G6PD-screening confirmation requirement and an indicative cost range.

Reserved for you.

This guide is informational, not medical or legal advice. The named-patient framework requires a licensed Indian physician's clinical judgment; Reserve Meds is the coordinator, not the prescriber.