

[Skip to main content](#)

[Home](#) / [Drugs](#) / [Krystexxa](#) / [In Pakistan](#)

Krystexxa access in Pakistan via the DRAP named-patient pathway

How patients in Pakistan obtain Krystexxa (pegloticase) for chronic gout refractory to conventional urate-lowering therapy, through the Drug Regulatory Authority of Pakistan Special Permission / Personal Use Import pathway. G6PD screening before initiation is mandatory.

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

1. Quick orientation

Krystexxa is the brand name for pegloticase, a pegylated recombinant porcine-like uricase enzyme that catalyzes the conversion of uric acid to allantoin, which the kidneys readily excrete. The US Food and Drug Administration first approved Krystexxa on September 14, 2010 for the treatment of chronic gout in adult patients refractory to conventional therapy. The label was expanded on July 7, 2022 to include co-administration with methotrexate based on the MIRROR randomized trial. In Pakistan, patients with chronic refractory tophaceous gout who have already failed allopurinol at the maximum tolerated dose and who have failed or cannot tolerate febuxostat face very few therapeutic options. The Drug Regulatory Authority of Pakistan (DRAP) Special Permission / Personal Use Import pathway, filed through the Online Import and Export System (OIES) portal, is the lawful route once a Pakistan Medical and Dental Council (PMDC) licensed rheumatologist or internist has decided this is the right next step. Reserve Meds is the US-side coordinator that aligns the sourcing, the cold-chain logistics, and the regulatory documentation kit. Reserved for you.

2. Why patients in Pakistan need Krystexxa via NPP

Krystexxa's international footprint is exceptionally narrow. The European Medicines Agency granted marketing authorisation for Krystexxa in January 2013 and the European Commission withdrew that authorisation in June 2016 at the marketing authorisation holder's request, on commercial rather than safety grounds. The EMA explicitly stated the withdrawal was not related to a safety or efficacy concern. Krystexxa has not been re-registered in the EU under Horizon or Amgen ownership, and is not registered in Japan, Canada, or in most Middle East and South Asia markets. There is no public record of DRAP registration of Krystexxa at the time of this review. For Pakistani patients with chronic refractory tophaceous gout, named-patient import is the primary legal pathway to access pegloticase.

The clinical population is small but the unmet need is intense. In refractory patients, tophi continue to grow, joints continue to erode, and quality of life deteriorates despite years of oral therapy. Pegloticase is uniquely effective at rapidly lowering serum uric acid to levels that mobilize and dissolve monosodium urate deposits. Pakistani families with relatives in the Gulf or with overseas remittance corridors often fund this care because the alternative is continued failure of an oral regimen that has not normalized serum uric acid. The named-patient pathway is the recognized regulatory route.

3. The DRAP Special Permission pathway for Krystexxa

DRAP regulates the import of medicines through the Quality Assurance and Laboratory Testing (QA<) Division's Import and Export Section. For unregistered medicines required by a specific patient, DRAP issues a Special Permission, also referred to as the No Objection Certificate (NOC) for Personal Use Import. Applications are filed through DRAP's Online Import and Export System (OIES).

For Krystexxa specifically, the application package contains:

- **Clinical justification letter** from the treating rheumatologist or internist, addressing chronic gout diagnosis refractory to conventional therapy, prior oral urate-lowering regimens attempted (allopurinol at maximum tolerated dose, febuxostat), reasons for failure or intolerance, tophus burden documented on imaging or examination, the rationale for IV uricase enzyme replacement, and the planned every-2-week dosing schedule with or without methotrexate co-administration.
- **PMDC licensure verification** for the treating physician in rheumatology, internal medicine, or a related specialty appropriate to manage refractory gout and IV biologic infusion.
- **Documented G6PD status.** This is non-negotiable. 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. The MENA and South Asian populations Reserve Meds coordinates for include groups with elevated G6PD-deficiency prevalence, and Pakistani populations specifically have higher background prevalence than many other geographies. The DRAP file must reflect that G6PD screening has been completed at the destination institution with a documented result before any procurement step is initiated.
- **Patient identifier:** CNIC for adult patients.
- **Product details** including brand name (Krystexxa), international nonproprietary name (pegloticase), manufacturer (Amgen Inc., current global rights holder following the Horizon Therapeutics acquisition on October 6, 2023), country of origin (USA), strength (8 mg pegloticase in 1 mL of sterile solution per single-dose vial), pack size, requested quantity for the initial sourcing window, lot, and expiry.
- **Destination dispensing facility license** showing the receiving infusion pharmacy is licensed to handle imported biologics with 2 to 8 degree Celsius cold-chain storage, an aseptic compounding capability for dilution into 250 mL of 0.9% or 0.45% sodium chloride for infusion, and trained staff to manage anaphylaxis and infusion reactions.
- **Manufacturer or authorized distributor letter** confirming the product is genuine and was sourced through the legitimate US specialty supply chain under DSCSA serialization.
- **Chain-of-custody plan** from the US specialty wholesaler through international air freight (validated 2 to 8 degree Celsius packaging with continuous temperature monitoring, light-protective) to the receiving Pakistani facility, including the freight forwarder, customs broker for FBR clearance at the Karachi seaport or Lahore airport, and importer of record.

Routine personal-use cases typically clear in four to eight weeks from a complete submission. Cases involving biologic enzyme products with anaphylaxis risk and G6PD screening prerequisites can extend to ten to sixteen weeks. Reserve Meds plans on the longer end and treats any faster turnaround as upside.

4. Where Krystexxa gets dispensed in Pakistan

Krystexxa requires a 2 to 8 degree Celsius cold-chain handoff, an aseptic compounding pharmacy capable of diluting the 8 mg vial into 250 mL of saline and administering the prepared infusion within 4 hours, an infusion suite capable of running the no-less-than-120-minute IV administration with full anaphylaxis-management capability (IV access, resuscitation drugs, trained staff), and a treating physician familiar with the premedication regimen (antihistamine, acetaminophen, IV corticosteroid). That capability set narrows the realistic dispensing footprint to tertiary centers. Aga Khan University Hospital (AKUH) in Karachi operates a 24/7 pharmacy network with temperature-controlled storage and the rheumatology and infusion infrastructure for biologic IV therapy. Liaquat National Hospital in Karachi, Shifa International Hospital in Islamabad, and Pakistan Kidney and Liver Institute (PKLI) in Lahore handle named-patient biologic imports as established workflows. The Combined Military Hospitals (CMH) network at Rawalpindi and Lahore treats military families and

civilian referrals at full tertiary capacity. Shaukat Khanum Memorial Cancer Hospital and Research Centre in Lahore, while flagship-positioned for oncology, holds the cold-chain pharmacy and aseptic compounding infrastructure that translates to IV biologic infusion.

The 2-week dosing cadence and the anaphylaxis-monitoring requirement effectively rule out smaller institutions without resuscitation infrastructure. Patients from Peshawar, Quetta, Multan, Faisalabad, or smaller cities typically travel to a major center for each infusion.

5. Real cost picture for Krystexxa in Pakistan

Three line items make up the patient-facing cost of a Krystexxa case sourced from the United States into Pakistan.

Drug acquisition. Per-vial WAC has risen substantially since the 2010 US launch. More recent regulatory and pricing references cite an annual WAC of approximately USD 650,000 for the standard every-2-week regimen, which implies a current per-infusion WAC in the range of USD 25,000 per vial. Exact per-vial WAC figures sit behind paywalled pricing databases at the time of this review, and the per-vial estimate should be confirmed at the time of any patient-specific quote. Reserve Meds quotes in USD as the primary currency because the Pakistani Rupee has been volatile. At the current USD to PKR range of approximately 278 to 280 as of May 2026, the per-infusion drug-only cost lands around PKR 7.0 million at the WAC reference, with annualized PKR equivalents above PKR 181 million.

International logistics surcharge. Validated 2 to 8 degree Celsius shipping with light-protective packaging, continuous temperature monitoring, customs documentation, and importer-of-record handling typically add USD 800 to USD 1,500 per shipment. Because dosing is every two weeks, shipment cadence and consolidation strategy meaningfully affect the annual logistics line. FBR customs clearance at the Karachi seaport or Lahore airport adds friction that experienced specialty importers manage routinely.

Coordination, documentation, and concierge fee. Reserve Meds quotes the concierge fee transparently on every case, with the rate disclosed on the firm quote rather than buried in a bundled total. The fee covers documentation kit preparation, US sourcing, cold-chain orchestration, customs paperwork, and a single named coordinator from intake through reorders.

Premedication consumables, aseptic compounding, infusion administration, methotrexate co-administration (where prescribed locally), and physician oversight are billed by the receiving Pakistani institution and are not part of the Reserve Meds quote. Local insurer behavior on named-patient imports is conservative: Adamjee, Jubilee, EFU, and State Life typically do not reimburse imported unregistered specialty drugs.

6. Typical timeline for Krystexxa in Pakistan

From the date the clinical justification letter is signed and the OIES file is submitted, routine DRAP review for Krystexxa typically runs four to eight weeks. Cases involving biologic enzyme products with anaphylaxis risk and G6PD prerequisites can extend toward ten to sixteen weeks while internal pharmacy committees onboard a new IV biologic with cold-chain handling and infusion-reaction protocols. Cold-chain transit adds approximately two to three days versus ambient air freight, so US-side procurement and validated packaging tend to overlap with DRAP review rather than wait for it. After the initial dose, the every-2-week dosing cadence sets the rhythm: each reorder window opens roughly two to three weeks before the next infusion. Most patients on pegloticase monotherapy discontinue within 6 to 12 months because of anti-PEG antibody formation, so Reserve Meds plans an initial sourcing window of 3 to 6 months and re-quotes as treatment continues. Methotrexate co-administration prescribed locally extends durable response.

7. What your physician needs to provide

The clinical justification letter is the cornerstone of the DRAP submission. For a Krystexxa Personal Use Import application, the letter typically covers the following.

- **Diagnosis and refractoriness.** Chronic gout with documentation of failure to normalize serum uric acid on conventional therapy. Failed therapies, doses attempted, and reasons for failure or intolerance. Tophus burden documented on imaging or clinical examination.
- **G6PD status.** Documented G6PD screening result for this patient. The contraindication for G6PD-deficient patients is absolute. Pakistani populations have higher background G6PD-deficiency prevalence than many other geographies, which raises the operational importance of this step.
- **Mechanism rationale.** Why pegylated recombinant porcine-like uricase is appropriate for this patient at this point in their course, in line with the FDA-labeled indication for refractory chronic gout.
- **Dosing plan.** 8 mg pegloticase IV every 2 weeks, infused over no less than 120 minutes. Premedication plan: antihistamine (such as fexofenadine the day before and the morning of infusion, plus IV diphenhydramine or equivalent), acetaminophen, IV corticosteroid (commonly methylprednisolone 125 mg or equivalent). If methotrexate co-administration is planned, document the oral methotrexate 15 mg weekly plus oral folic acid 1 mg daily regimen.
- **Monitoring plan.** Serum uric acid measured before each infusion. Discontinue 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. Anaphylaxis-management protocol documented at the infusion center.
- **Adverse-event reporting commitment.** The treating physician's commitment to report adverse events through the DRAP Pharmacovigilance Centre, signed under the PMDC license.

8. Common questions about Krystexxa in Pakistan

Is G6PD deficiency a contraindication? Yes. 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. Background G6PD-deficiency prevalence is elevated in Pakistani populations relative to many other geographies, which makes documented screening at the destination clinical team non-negotiable before any infusion is scheduled.

Will Adamjee, Jubilee, EFU, or State Life cover Krystexxa? Coverage for named-patient imports of unregistered drugs is uncommon across Pakistani health plans. Some plans pay a partial percentage on a case-by-case basis. Reserve Meds supplies the documentation an insurer would need to assess a claim; the claim itself is yours or your hospital's to file. The realistic default is cash-pay.

How does Sehat Sahulat interact with a Krystexxa case? The Sehat Sahulat Program's annual ceiling of Rs. 1,000,000 per family typically does not stretch to cover US-sourced specialty biologics. Patients can still use Sehat Sahulat for hospitalization, supportive care, and joint procedures while Krystexxa is procured separately on a cash-pay basis.

Can Krystexxa be infused at home? No. Krystexxa is administered only in supervised settings capable of managing anaphylaxis. The FDA label carries a boxed warning for anaphylaxis and infusion reactions. Direct-to-home infusion is not the model.

What is the monitoring requirement? Serum uric acid is measured before each infusion. A rising pre-infusion sUA, particularly above 6 mg/dL on two consecutive measurements, signals loss of response and triggers discontinuation per the label. Patients are screened for G6PD deficiency before initiation.

Is there an 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.

9. Where Reserve Meds fits in Krystexxa cases

Reserve Meds has no prior Pakistan Krystexxa case experience as of the review date. Standard NPP coordination applies, with particular attention to five operational realities specific to this product. G6PD screening at the receiving clinical team is non-negotiable before any infusion is scheduled, and the elevated background prevalence in Pakistani populations sharpens this point. Cold-chain integrity from US specialty wholesaler through FBR customs at 2 to 8 degrees Celsius with light-protective packaging. Infusion-center identification as part of case workup, not as an afterthought, with full anaphylaxis-management capability. Premedication and methotrexate co-administration prescribed and managed locally by the treating physician (Reserve Meds does not coordinate the methotrexate side). Per-vial pricing quoted at the time of inquiry after live source verification because the WAC trajectory and the absence of public real-time per-vial figures argue against any cached figure. The clinical decisions remain with the PMDC-licensed treating physician. The regulatory authority remains DRAP. The dispensing remains with the licensed Pakistani facility. Reserve Meds is the connective tissue between the US specialty wholesaler and those three Pakistani pillars, with a single named coordinator who stays with the case through reorders.

10. Next step

If you have a chronic refractory gout patient in your family with documented G6PD status and a treating physician in Pakistan ready to write the clinical justification letter, the next step is to add your case to the waitlist so Reserve Meds can confirm eligibility within 24 to 48 hours and send the documentation kit to your physician and hospital pharmacy.

Reserved for you.

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Review and 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](#) >

Last medically reviewed: 2026-05-12.