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# Krystexxa access in Saudi Arabia via the SFDA named-patient pathway

How patients in the Kingdom of Saudi Arabia obtain Krystexxa (pegloticase) for chronic refractory gout, through the Saudi Food and Drug Authority Personal Importation Program, with mandatory G6PD screening built into the pre-treatment workup.

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

## 1. Quick orientation

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Krystexxa is the brand name for pegloticase, a pegylated recombinant porcine-like uricase enzyme delivered as a 2-hour IV infusion every 2 weeks. The US Food and Drug Administration first approved Krystexxa on September 14, 2010 for adults with chronic gout refractory to conventional therapy, and the FDA approved a 2022 supplemental BLA expanding the label to include co-administration with methotrexate based on the MIRROR randomized controlled trial. Krystexxa is not commercially registered in Saudi Arabia, and EMA withdrew the EU marketing authorisation in 2016 on commercial rather than safety grounds, which means most non-US patients reach pegloticase through named-patient routes. For Saudi patients with chronic refractory tophaceous gout whose treating rheumatologist has identified Krystexxa as the appropriate next step, the SFDA Personal Importation Program (PIP) is the lawful, documented route. Reserve Meds is the US-side coordinator. One critical pre-treatment step is non-negotiable for the Saudi population: G6PD deficiency screening. Reserved for you.

## 2. Why patients in Saudi Arabia need Krystexxa via NPP

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Krystexxa sits in an unusually clean named-patient profile for international cases. The drug is not commercially registered in Saudi Arabia or in most Middle East and South Asia markets. The EMA withdrew the EU marketing authorisation in 2016 at the request of the then-marketing authorisation holder, on commercial rather than safety grounds, and the product has not been re-registered in the EU under subsequent ownership. UK MHRA, PMDA, and Health Canada do not have Krystexxa as a commercially marketed product.

Patients with chronic refractory tophaceous gout, who have already failed allopurinol at maximum tolerated dose and failed or cannot tolerate febuxostat, have very few therapeutic options. In many of these 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. The clinical population in KSA is small but the unmet need is intense, particularly in patients with visible tophi causing disability.

The MENA dimension makes pre-treatment workup particularly important. 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, which is an absolute contraindication to Krystexxa because of the risk of life-threatening hemolytic reactions and methemoglobinemia. The high prevalence of G6PD deficiency in the Saudi population, particularly in the Eastern Province and among patients with familial origins in surrounding regions, means G6PD screening is not an afterthought but a gating step in the case workup.

Reserve Meds positions Krystexxa as a Tier-1 access case where the operational drivers are unbroken cold-chain handling, infusion-center identification with anaphylaxis-management capability, and documented G6PD screening before the first dose is scheduled.

### 3. The SFDA Personal Importation Program for Krystexxa

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The SFDA Personal Importation Program allows a KSA-licensed physician to request import of a specific medicine for a specific named patient when the medicine is approved by a recognized reference authority (US FDA for Krystexxa) and a clinically equivalent locally registered alternative is not suitable. The framework explicitly contemplates rheumatologic and rare-disease therapies. Applications are filed through the dispensing institution's import pharmacy and reviewed by SFDA's Drug Sector, with named-patient activity increasingly routed through the agency's Ghad digital regulatory platform.

For Krystexxa specifically, the application package contains:

- **Clinical justification letter** from the treating rheumatologist, addressing diagnosis with ICD-10 coding (M10.x for gout subtypes, with tophaceous gout documentation where applicable), prior therapy with allopurinol at maximum tolerated dose with the dose, duration, and outcome, prior therapy with or intolerance of febuxostat where applicable, and the rationale for uricase replacement therapy.
- **SCFHS licensure verification** in rheumatology or internal medicine appropriate to manage chronic refractory gout and to oversee Krystexxa infusion therapy.
- **G6PD screening documentation.** This is the most important single piece of documentation in a Saudi Krystexxa PIP file. The patient must have a documented quantitative G6PD assay result before any procurement step is taken. Krystexxa is contraindicated in G6PD-deficient patients. The PIP file should include the laboratory report and the treating physician's explicit statement that G6PD deficiency has been ruled out.
- **Patient identifier** in the format SFDA requires, typically an anonymized internal reference linked to the national ID inside the hospital record.
- **Product details** including brand name (Krystexxa), international nonproprietary name (pegloticase), manufacturer (Amgen Inc., current global rights holder after the 2023 Horizon Therapeutics acquisition), country of origin (USA), strength (8 mg pegloticase in 1 mL single-dose vial), requested quantity, lot, and expiry.
- **Destination dispensing facility license** showing the receiving infusion pharmacy is SFDA-licensed to handle imported biologics with cold-chain storage and aseptic compounding capability.
- **Chain-of-custody plan** from the US specialty wholesaler through international transit with validated 2 to 8 degree Celsius packaging, continuous temperature monitoring, and light-protective handling, to the receiving Saudi pharmacy, including freight forwarder, customs broker, and importer of record.

Approval timelines for routine cases typically run 10 to 21 business days. Complex cases can extend to 6 to 10 weeks. SFDA does not publish guaranteed turnaround times.

### 4. Where Krystexxa gets dispensed in Saudi Arabia

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Krystexxa requires a 2 to 8 degree Celsius cold-chain handoff, an infusion pharmacy that can compound the IV bag (250 mL of 0.9 percent or 0.45 percent sodium chloride injection) under aseptic technique within 4 hours of dilution, and a supervised infusion setting capable of managing anaphylaxis (IV access, resuscitation drugs, trained staff for the 2-hour infusion and post-infusion observation). That capability set narrows the realistic dispensing footprint. In Saudi Arabia, the institutions with the rheumatology coverage, the infusion-suite anaphylaxis readiness, the G6PD screening laboratory infrastructure, and the import pharmacy workflow to handle Krystexxa include King Faisal Specialist Hospital and Research Centre (KFSH&RC) in Riyadh, Jeddah, and Madinah; King Abdulaziz Medical City (KAMC) and the Ministry of National Guard Health Affairs (MNGHA) network; King Saud University Medical City (KSUMC) and KSAU-HS affiliated centers; the Dr. Sulaiman Al Habib Medical Group (HMG) network; Saudi German Health facilities; Dr. Soliman Fakeeh Hospital in Jeddah; and Dallah Hospital in Riyadh.

Smaller hospitals without internal import pharmacy capacity or infusion-suite anaphylaxis readiness typically route Krystexxa cases through one of these centers, or through an SFDA-licensed specialty importer based in Riyadh or Jeddah.

## 5. Real cost picture for Krystexxa in Saudi Arabia

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

**Drug acquisition.** Public WAC data points indicate that Krystexxa's per-vial price has risen substantially since launch. At US launch in 2010, the WAC was approximately USD 2,300 per 8 mg vial; 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. At WAC reference, that translates to roughly SAR 2.44 million annualized. Exact current per-vial WAC sits behind paywalled pricing databases, so Reserve Meds confirms pricing at the time of any patient-specific quote.

**International logistics surcharge.** Validated 2 to 8 degree Celsius shipping with continuous temperature monitoring and light-protective packaging, plus customs documentation and importer-of-record handling, typically adds SAR 3,000 to SAR 9,000 per shipment. Because dosing is every 2 weeks on a chronic basis, Reserve Meds plans repeat-shipment cadence at case acceptance.

**Coordination, documentation, and concierge fee.** Reserve Meds quotes the concierge fee transparently on every case, with the rate disclosed on the firm quote. The fee covers documentation kit preparation (including the G6PD review), US sourcing through DSCSA-compliant US specialty wholesalers, cold-chain orchestration, customs paperwork, and a single named coordinator from intake through reorders.

Local rheumatology visits, G6PD screening laboratory work, methotrexate co-administration management, premedication (antihistamines, acetaminophen, and an IV corticosteroid before each infusion), the 2-hour infusion administration, post-infusion observation, and serum uric acid monitoring before each infusion are billed by the receiving Saudi institution and are not part of the Reserve Meds quote. Local insurer behavior on Krystexxa varies. Bupa Arabia, Tawuniya, and MedGulf each handle named-patient imports case-by-case under the Council of Cooperative Health Insurance (CCHI) framework, with pre-authorization typically required.

## 6. Typical timeline for Krystexxa in Saudi Arabia

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From the date the clinical justification letter and the G6PD report are submitted, routine SFDA review for Krystexxa typically runs 10 to 21 business days. First-time Krystexxa imports at an institution can extend toward the 6 to 10 week range while internal committees and the importer onboard a new cold-chain biologic. Cold-chain transit adds approximately 2 to 3 days versus ambient air freight. After the initial dose, the every-2-week dosing cadence sets the rhythm. 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. Reserve Meds plans a first-tranche multi-dose shipment to bridge the early phase and then re-quotes ongoing access as the clinical response trajectory becomes clear.

## 7. What your physician needs to provide

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The clinical justification letter is the cornerstone of the SFDA submission. For a Krystexxa PIP application, the letter typically covers the following.

- **Diagnosis.** Chronic gout, with tophaceous documentation where applicable, ICD-10 coded.
- **Prior therapy history.** Allopurinol at the maximum tolerated dose with the dose, duration, and outcome (failure to normalize serum uric acid). Febuxostat outcome where attempted, including any intolerance or contraindication.
- **Refractory status documentation.** The FDA-labeled population is adults who have 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 are contraindicated.
- **G6PD screening result.** A quantitative G6PD assay result documenting that the patient is not G6PD-deficient. This is the most important single document in a Saudi Krystexxa file. Krystexxa is contraindicated in G6PD deficiency.

- **Dosing plan.** 8 mg IV every 2 weeks, infused over no less than 120 minutes. Premedication regimen including an antihistamine (such as fexofenadine the day before and the morning of infusion, plus IV diphenhydramine or equivalent), acetaminophen, and an IV corticosteroid (commonly methylprednisolone 125 mg or equivalent). Methotrexate co-administration plan per the 2022 label update where applicable (15 mg oral weekly plus oral folic acid 1 mg daily).
- **Monitoring plan.** Serum uric acid measured before each infusion. Discontinuation trigger per the FDA label when sUA rises above 6 mg/dL on two consecutive measurements before the next infusion, which signals anti-PEG antibody formation and elevated infusion-reaction risk. Anaphylaxis-management readiness at the infusion suite for each dose.
- **Adverse-event reporting commitment.** The treating physician's commitment to report any adverse event through the SFDA National Pharmacovigilance Center, signed under the SCFHS license.

Reserve Meds supplies a documentation kit that maps each of these elements to the SFDA-required sections, with the G6PD screening evidence treated as the gating document in the file review.

## 8. Common questions about Krystexxa in Saudi Arabia

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**Why does G6PD screening matter so much in Saudi Arabia?** The FDA label specifically flags patients of African, Mediterranean (including Middle Eastern), and Southern Asian ancestry as at increased risk for G6PD deficiency. The prevalence of G6PD deficiency in the Saudi population, particularly in the Eastern Province, is high enough that screening is not optional. Krystexxa is contraindicated in G6PD-deficient patients because of life-threatening hemolytic reactions and methemoglobinemia.

**Will Bupa Arabia, Tawuniya, or MedGulf cover Krystexxa?** Each plan handles named-patient imports case-by-case under CCHI rules. Pre-authorization is typically required, and reimbursement, where available, often comes after the fact through the patient's own claim. Cash-pay is the default operating posture.

**Can a Ministry of Health rheumatologist sign the PIP letter?** Yes. KSA-licensed rheumatologists at Ministry of Health hospitals, KFSH&RC, KAMC, MNGHA, and other public-sector institutions have full signing authority on PIP applications under their SCFHS license, as do private-sector rheumatologists at HMG, Saudi German, Fakeeh, Dallah, and similar institutions.

**Can Krystexxa be infused at home?** No. Krystexxa carries a boxed warning for anaphylaxis and is administered only in supervised settings capable of managing anaphylaxis, which in practice means hospital infusion centers, rheumatology infusion suites, and qualified specialty infusion centers. Patients must be premedicated and monitored.

**What is the safety profile?** The Krystexxa label carries a boxed warning for anaphylaxis and infusion reactions, and for G6PD deficiency-associated hemolysis and methemoglobinemia. Anaphylaxis was reported in approximately 6.5 percent of patients on the every-2-week regimen in pre-marketing trials. Co-administration with methotrexate reduces infusion-reaction frequency substantially based on MIRROR data.

**What is the typical course duration?** There is no fixed end point. Treatment continues every 2 weeks as long as serum uric acid remains controlled. Many patients on pegloticase monotherapy discontinue within months because of anti-PEG antibody formation. Methotrexate co-administration extends durable response.

## 9. Where Reserve Meds fits in Krystexxa cases

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Reserve Meds has no prior Saudi Krystexxa case experience as of the review date. Standard NPP coordination applies, with several drug-specific operating notes: validated 2 to 8 degree Celsius cold-chain across multi-leg transit; receiving infusion center capable of compounding and administering the IV bag under aseptic technique within 4 hours of dilution; G6PD screening at the receiving clinical team treated as a gating document before any shipment is scheduled (Reserve Meds does not screen patients, but the coordinator confirms that the receiving physician has documented G6PD status before

procurement); and locally managed premedication and methotrexate co-administration handled by the treating rheumatologist. The clinical decisions remain with the SCFHS-licensed rheumatologist. The regulatory authority remains SFDA. The dispensing remains with the licensed Saudi infusion pharmacy. Reserve Meds is the connective tissue between the US specialty wholesaler and those three Saudi pillars.

## 10. Next step

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If your treating rheumatologist in Saudi Arabia has identified Krystexxa as the appropriate next step for chronic refractory gout, and the G6PD screening is either complete or scheduled, the next step is to add your case to the waitlist so Reserve Meds can confirm eligibility within 24 to 48 hours, review the G6PD documentation, and send the documentation kit to your physician.

*Reserved for you.*

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