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Krystexxa access in Egypt: the EDA Personal Importation pathway

How adults in Egypt with chronic refractory gout legally obtain Krystexxa (pegloticase) from US-source supply, with mandatory G6PD screening before initiation.

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

Quick orientation

Krystexxa (pegloticase) is a pegylated recombinant uricase enzyme approved by the US Food and Drug Administration in September 2010 for the treatment of chronic gout in adults refractory to conventional therapy (allopurinol or febuxostat at maximum tolerated dose). In July 2022 the label was expanded to include co-administration with methotrexate based on the MIRROR randomised controlled trial. Krystexxa is administered as an intravenous infusion every 2 weeks in a supervised setting capable of managing anaphylaxis. In Egypt, Krystexxa is not commercially registered, and Egyptian rheumatologists treating patients with chronic refractory tophaceous gout reach the medicine through the Egyptian Drug Authority (EDA) Personal Importation pathway under Law No. 151 of 2019. Reserve Meds handles the US-side sourcing, cold-chain logistics, and the documentation kit your physician needs, with one operational pre-condition that is not optional in the Egyptian context: documented G6PD screening before any infusion is scheduled.

Reserved for you.

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

Krystexxa's international footprint is exceptionally narrow. The European Medicines Agency granted marketing authorisation in January 2013 and the European Commission withdrew that authorisation in June 2016 at the manufacturer's request, on commercial rather than safety grounds. The medicine has not been re-registered in the EU under Horizon or Amgen ownership. Krystexxa is not registered in Japan via PMDA or in any GCC, MENA, or South Asian commercial market. For Egyptian patients, the structural reality is that pegloticase is not on the EDA register, no licensed Egyptian importer holds commercial inventory, and no hospital pharmacy stocks the product. Named-patient import is the primary legal pathway to access in Egypt.

The clinical population that reaches for Krystexxa in Egypt is small but the unmet need is intense. Chronic refractory gout patients have already failed allopurinol at maximum tolerated dose and either failed or cannot tolerate febuxostat. 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 mobilise and dissolve monosodium urate deposits. Egyptian rheumatology programmes at Cairo University, Ain Shams, and private specialty hospitals do see these refractory tophaceous gout cases, often in older male patients with longstanding hyperuricemia and visible joint deformity. The narrow biologic mechanism, the cold-chain shipping requirement, the IV infusion administration with anaphylaxis-management capacity, and the absence of commercial registration outside the United States together place this case profile clearly inside the named-patient lane rather than any commercial import channel.

One Egypt-specific element matters more than for most other drugs Reserve Meds coordinates: G6PD deficiency screening. 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. The Egyptian population sits squarely in this risk band, and G6PD deficiency is a hard contraindication because of the risk of life-threatening hemolytic reactions and methemoglobinemia. Screening before initiation is not optional, and the documented result must be in the patient file before any procurement step.

The EDA named-patient pathway for Krystexxa

The Egyptian Drug Authority was created by Law No. 151 of 2019. EDA permits importation of unregistered medicines for a specific patient where no equivalent registered product is available locally or where the available quantity cannot meet the patient's clinical need. The application is filed through the dispensing institution's import pharmacy, which for Krystexxa is typically a hospital rheumatology programme with an in-house infusion suite, or a Cairo-based licensed specialty importer routing to a qualified rheumatology infusion centre.

A complete Krystexxa application typically includes:

- A clinical justification letter from the treating rheumatologist, original, stamped, on hospital letterhead, stating the diagnosis of chronic gout refractory to conventional therapy per the FDA-approved indication (failure to normalise serum uric acid and inadequate symptom control on xanthine oxidase inhibitors at maximum medically appropriate dose, or contraindication to allopurinol and febuxostat), the patient's tophi burden and joint involvement, and prior urate-lowering therapy history
- Documentation of G6PD status (this is the threshold document: G6PD deficiency is a hard contraindication, and Reserve Meds will not initiate procurement without a documented result in the patient file)
- The treating physician's Egyptian Medical Syndicate membership number and Ministry of Health licence reference
- A recent prescription specifying brand name (Krystexxa), generic name (pegloticase), strength (8 mg per mL single-dose vial), and the fixed every-2-week 8 mg IV infusion regimen with the premedication and infusion-rate plan (no less than 120 minutes)
- A patient identifier (national ID or passport copy)
- Product details: Amgen Inc. (current global rights holder after the October 2023 Horizon Therapeutics acquisition), country of origin, FDA approval reference, shelf life, and the 2 to 8 degree Celsius storage condition
- The destination dispensing facility licence number, with confirmation that the receiving infusion centre is equipped to manage anaphylaxis (IV access, resuscitation drugs, trained staff) and to compound the IV bag under aseptic technique
- A chain-of-custody plan describing how Krystexxa will move under continuous 2 to 8 degree Celsius cold chain from a US specialty distributor through air freight to Cairo International Airport with documented temperature logging at every handoff

For Krystexxa, the G6PD result is the single most important document after the clinical justification letter. The strongest applications include the most recent serum uric acid trend (because the label recommends discontinuing if sUA rises above 6 mg/dL on two consecutive measurements before the next infusion, signalling loss of response from anti-PEG antibody formation), the premedication protocol (antihistamine the day before and morning of infusion, IV diphenhydramine or equivalent, acetaminophen, and IV corticosteroid such as methylprednisolone 125 mg), and where the prescribing rheumatologist plans co-administration with methotrexate (oral 15 mg weekly plus oral folic acid 1 mg daily per the MIRROR-based 2022 label update), that protocol is described in the file. Routine EDA personal-import authorisations are typically processed in 3 to 6 week windows, with first-time biologic imports potentially extending to 8 to 14 weeks.

Where Krystexxa gets dispensed in Egypt

Krystexxa requires an infusion centre with anaphylaxis-management capacity (IV access, resuscitation drugs, trained staff for an event that occurred in approximately 6.5 percent of patients on the every-2-week regimen in pre-marketing trials), aseptic IV compounding, and rheumatology supervision. The Egyptian institutions that fit this profile include Cairo University Hospitals (Kasr Al Ainy), the oldest and largest academic hospital network in Egypt and the Middle East, with dedicated rheumatology services and an institutional import workflow; Ain Shams University Hospitals, the second major academic hospital network in Cairo with strong rheumatology and routine imported-specialty-drug experience; Dar Al

Fouad Hospital in 6th of October City, JCI-accredited since 2005 with strong infusion-centre infrastructure; As-Salam International Hospital in Cairo; and the Cleopatra Hospitals Group, the largest private hospital group in Egypt.

Children's Cancer Hospital Egypt 57357 is a pediatric oncology hospital and is not the appropriate route for chronic refractory gout, which is an adult disease. Magdi Yacoub Heart Foundation is a cardiovascular centre and is similarly outside the rheumatology scope. For families outside Cairo and Giza, the practical pattern is referral to a Cairo-based rheumatology programme with cooperation from the regional rheumatologist where applicable.

Real cost picture for Krystexxa in Egypt

Reserve Meds quotes patients in US dollars and accepts USD wire transfers. The Egyptian pound has lost more than 70 percent of its value against the US dollar since early 2022, with the USD/EGP rate near 52 to 53 in May 2026. Quoting in USD insulates the patient from intra-case currency drift. Public WAC data points indicate that Krystexxa's per-vial price has risen substantially since 2010 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 per-infusion WAC in the range of USD 25,000 per vial. Exact current per-vial WAC sits behind paywalled pricing databases and Reserve Meds confirms live source verification at the time of any patient-specific quote.

The drug cost is the dominant line item. International cold-chain logistics from a US specialty distributor to Cairo International Airport typically run USD 600 to 1,500 per shipment, depending on volume and urgency. EDA permit fees and Egyptian customs charges sit on the dispensing facility's side. Infusion centre costs (IV access, premedication administration, 120-minute infusion plus observation, serum uric acid monitoring before each dose, methotrexate co-administration where prescribed and managed locally) sit on the hospital ledger. Reserve Meds itemises the US-side drug procurement, the international logistics, and the concierge coordination fee separately on every firm quote, never bundled.

On the insurance side, Bupa Egypt, AXA Egypt, MetLife Egypt, Allianz Egypt, and Misr Insurance each assess named-patient imports case by case. Krystexxa is not on standard formularies in EU, UK, or GCC markets, which means pre-authorization requirements are stringent and reimbursement outcomes are variable. UHIA coverage of specialty rheumatology imports of this unit cost is not the operating path in 2026. Cash-pay remains the dominant posture.

Typical timeline for Krystexxa in Egypt

For a routine Egyptian Krystexxa case with complete documentation including the G6PD result, the EDA personal-import window is typically 3 to 6 weeks. The biologic class extends operational logistics by 2 to 3 days beyond ambient-product shipments because of validated 2 to 8 degree Celsius packaging and continuous temperature monitoring through Cairo International Airport. A first-time import at a given Egyptian rheumatology centre may add 2 to 3 weeks for institutional pharmacy onboarding. Because Krystexxa is dosed every 2 weeks on a chronic basis with no fixed end point, Reserve Meds plans repeat-shipment cadence (typically monthly with two vials per shipment) at case acceptance rather than treating each infusion as a one-off. Loss of response signalled by rising pre-infusion sUA above 6 mg/dL on two consecutive measurements is the clinical trigger to reassess and is handled by the treating rheumatologist.

What your physician needs to provide

The clinical justification letter is the cornerstone of the EDA application and, for Krystexxa, the strongest letters consistently include: a confirmed diagnosis of chronic gout refractory to conventional therapy, with documentation of failure or contraindication to allopurinol and febuxostat at maximum medically appropriate dose; the patient's tophi burden and joint involvement; the documented G6PD status (this is a contraindication threshold and must be confirmed before initiation given the Egyptian population's elevated risk band per the FDA label); the proposed fixed-dose IV regimen (8 mg every 2 weeks, infusion no less than 120 minutes); the premedication protocol; the planned methotrexate co-administration regimen where applicable (oral 15 mg weekly plus oral folic acid 1 mg daily, prescribed and managed locally); the planned serum uric acid monitoring schedule (before each infusion, with discontinuation triggered if sUA exceeds 6 mg/dL on two

consecutive measurements); and the prescribing physician's EMS membership and Ministry of Health licence verification matched to the infusion centre.

The treating physician retains the clinical decision and the pharmacovigilance reporting obligation through EPVC, using either the Yellow Card or CIOMS forms. Reserve Meds supplies the structured documentation template and the chain-of-custody packet. We do not write the clinical letter, do not screen for G6PD deficiency, and do not file adverse-event reports. The infusion centre's anaphylaxis-management readiness is the responsibility of the local clinical team, and Reserve Meds confirms it is in place as part of intake review.

Common questions about Krystexxa in Egypt

Why is G6PD screening required before Krystexxa in Egypt?

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. The Egyptian population sits in this elevated risk band. Documented G6PD screening before initiation is mandatory in every Krystexxa case Reserve Meds coordinates for an Egyptian patient.

Will Bupa Egypt, AXA Egypt, MetLife Egypt, or Allianz Egypt cover Krystexxa?

Each insurer assesses named-patient rheumatology imports case by case. Krystexxa's unit cost and absence from EU and GCC formularies typically mean stringent pre-authorization. Reserve Meds supplies the documentation set; the claim filing stays with you or the dispensing hospital. Cash-pay is the default posture and many Egyptian families reimburse themselves later if coverage applies.

What is the anaphylaxis risk?

The Krystexxa label carries a boxed warning for anaphylaxis and infusion reactions, and for G6PD deficiency associated hemolysis and methemoglobinemia. Anaphylaxis occurred in approximately 6.5 percent of patients on the every-2-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 reduces infusion reaction frequency substantially based on MIRROR data (4 percent versus 31 percent on pegloticase alone). The infusion centre must be equipped to manage anaphylaxis.

How long does treatment last?

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 6 to 12 months because of anti-PEG antibody formation. Methotrexate co-administration extends durable response. The label recommends discontinuing if sUA rises above 6 mg/dL on two consecutive pre-infusion measurements, because continued dosing in that setting increases the risk of infusion reactions and anaphylaxis.

Is there an alternative to Krystexxa?

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. The decision to escalate to pegloticase is a treating-rheumatologist clinical decision.

Our family is split between Cairo and the Gulf. Can you coordinate in both places?

Yes. Reserve Meds runs the patient-side coordination in Arabic where requested and the family-side coordination in English in parallel, with a single named coordinator. We support family correspondence across the UAE, Saudi Arabia, the UK, North America, and elsewhere in the Egyptian diaspora.

Where Reserve Meds fits in Krystexxa cases

Reserve Meds is a US-based concierge coordinator. We do not replace your rheumatologist, do not replace EDA, and do not act as an Egyptian importer of record. What we do is orchestrate the US-side specialty distributor sourcing under DSCSA serialization with full pedigree, prepare validated 2 to 8 degree Celsius cold-chain logistics with continuous temperature monitoring through Cairo International Airport, and assemble the documentation kit your physician needs for the EDA Personal Importation filing. The G6PD result is a Reserve Meds intake threshold and procurement does not start until it is in the file. Because Krystexxa is dosed every 2 weeks on a chronic basis, Reserve Meds plans repeat-shipment cadence at case acceptance. Krystexxa has no prior Reserve Meds case experience as of this review, so the operating posture is standard NPP coordination with particular attention to G6PD documentation, cold-chain integrity, infusion-centre anaphylaxis-management readiness, and serum uric acid monitoring discipline.

Next step

If an adult family member in Egypt has chronic refractory gout after failing allopurinol and febuxostat, the treating rheumatologist is considering Krystexxa, and documented G6PD screening is available or can be arranged, add the case to the waitlist. We will respond within 24 to 48 hours with a documentation kit for your physician and an indicative cost range in USD.

Reserved for you.

This guide is informational, not medical or legal advice. The Personal Importation framework requires a licensed Egyptian physician's clinical judgment, and G6PD screening is mandatory before initiation; Reserve Meds is the coordinator, not the prescriber.