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Revuforj access in Egypt: the EDA Personal Importation pathway

How adult and pediatric patients in Egypt with relapsed or refractory KMT2A-translocated or NPM1-mutated acute leukemia legally obtain Revuforj (revumenib) from US-source supply.

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

Quick orientation

Revuforj (revumenib) is the first-in-class oral menin inhibitor approved by the US Food and Drug Administration in November 2024 for relapsed or refractory acute leukemia with a KMT2A translocation (KMT2Ar) in adult and pediatric patients 1 year of age and older. In October 2025 the label was expanded to include relapsed or refractory acute myeloid leukemia with a susceptible NPM1 mutation. Revuforj is the first and only approved menin inhibitor, has no generic, and is pediatric-eligible from age 1. In Egypt, Revuforj has no public record of registration with the Egyptian Drug Authority (EDA), and Egyptian hematology and pediatric oncology centres reach the medicine through the EDA Personal Importation pathway under Law No. 151 of 2019. Reserve Meds handles the US-side sourcing through Syndax-authorized channels, international logistics, and the documentation kit your physician needs.

Reserved for you.

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

KMT2A-rearranged acute leukemia is rare. It accounts for a small minority of adult AML and a larger fraction of infant and pediatric ALL. The absolute patient count in any individual Egyptian centre is small, which discourages local stocking and slows the regulatory ROI calculation for a manufacturer to register country by country. Revuforj is first-in-class with no therapeutically equivalent local substitute that an Egyptian hematologist or pediatric oncologist can prescribe instead. The pediatric eligibility from age 1 is unusual for a novel targeted oncology therapy and is one of the operational reasons Reserve Meds expects this drug to surface in Egypt: Children's Cancer Hospital Egypt 57357, opened in 2007, is the largest pediatric oncology hospital in the world by bed count and houses Egypt's most advanced pediatric AML and ALL programmes, with a Personalised Medication Management Unit that is the first pharmacogenetics unit of its kind in Egypt and the Arab world.

The structural access gap in Egypt shows up in the same pattern as for other launch-phase rare-disease oncology agents. Revuforj is approved by the FDA in the United States only, with an EMA submission in progress at this review date and no marketing authorisation issued anywhere outside the US. There is no SFDA, MOHAP, or CDSCO registration in MENA or South Asia. In Egypt, this means the medicine is not on the EDA register, no licensed Egyptian importer holds commercial inventory, and no hospital pharmacy stocks the product. For an adult or pediatric patient with relapsed or refractory KMT2A-rearranged acute leukemia, or NPM1-mutated AML, the Personal Importation pathway is the legal route. The clinical urgency is high because relapsed or refractory acute leukemia carries poor outcomes, and the molecular rationale (KMT2A-rearranged leukemias depend on the menin-KMT2A interaction to drive their leukemogenic transcriptional program) makes Revuforj mechanistically targeted at the disease driver in a way standard regimens are not.

The EDA named-patient pathway for Revuforj

The Egyptian Drug Authority was created by Law No. 151 of 2019. EDA is a public service authority affiliated to the Prime Minister, with the Drug Registration Sector handling registration files and the Egyptian Pharmacovigilance Center (EPVC)

handling post-market safety. 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. This is the Personal Importation pathway. The application is filed through the dispensing institution's import pharmacy, which for Revuforj is typically 57357 (for pediatric cases), Kasr Al Ainy or Ain Shams (for adult cases), or a Cairo-based licensed specialty importer acting on the patient's behalf.

A complete Revuforj application typically includes:

- A clinical justification letter from the treating hematologist or pediatric oncologist, original, stamped, on hospital letterhead, stating the diagnosis (acute leukemia with confirmed KMT2A translocation or, for AML, a susceptible NPM1 mutation), the molecular confirmation report (cytogenetics, FISH, or molecular testing showing the KMT2Ar fingerprint or the specific NPM1 mutation), the relapsed or refractory disease state, prior therapies, and why Revuforj is the appropriate next-line therapy
- The treating physician's Egyptian Medical Syndicate membership number and Ministry of Health licence reference
- A recent prescription specifying brand name (Revuforj), generic name (revumenib), strength (110 mg or 160 mg film-coated tablets), and the weight-based dosing plan (270 mg orally twice daily for patients 40 kg or more; 160 mg/m² orally twice daily for patients under 40 kg; with CYP3A4 inhibitor co-administration adjustment if applicable)
- A patient identifier (national ID or passport copy, with pediatric-specific weight and body surface area documentation where relevant)
- Product details: Syndax Pharmaceuticals (Waltham, Massachusetts), country of origin, FDA approval reference, shelf life, and the controlled-room-temperature storage condition
- The destination dispensing facility licence number
- A chain-of-custody plan describing how Revuforj will move from a Syndax-authorized US specialty pharmacy partner through international air courier to Cairo International Airport, with DSCSA serialization and full pedigree documentation

For Revuforj, the molecular confirmation report is the cornerstone document. Without confirmed KMT2A translocation or NPM1 mutation, the indication is not met and the application will not pass clinical review. The strongest applications include the patient's full prior-therapy sequence (induction regimen, prior consolidation, prior salvage attempts, and any consideration of allogeneic hematopoietic stem cell transplant), the differentiation syndrome surveillance plan for the first 28 days of treatment, the ECG and electrolyte monitoring plan (baseline, weekly for the first month, monthly thereafter), and the proposed concomitant medication review for CYP3A4 inhibitors (azole antifungals such as posaconazole or voriconazole are clinically common in acute leukemia and require dose adjustment to 160 mg twice daily for patients 40 kg or more, or 95 mg/m² twice daily for patients under 40 kg). Routine EDA personal-import authorisations for well-documented hematology cases are typically processed in 3 to 6 week windows. Pediatric cases at 57357 with molecular confirmation in the patient file tend to move on the faster end of the range.

Where Revuforj gets dispensed in Egypt

Revuforj is an oral room-temperature tablet, which simplifies dispensing logistics relative to biologics. What it requires is a hematology or pediatric oncology programme capable of managing differentiation syndrome and QT-interval prolongation, with regular CBC, chemistry, and ECG monitoring infrastructure. The Egyptian institutions that fit this profile and routinely handle named-patient hematology imports include Children's Cancer Hospital Egypt 57357 in Cairo, the largest pediatric oncology hospital in the world by bed count and the primary route for pediatric KMT2Ar leukemia cases in Egypt, with a Personalised Medication Management Unit; Cairo University Hospitals (Kasr Al Ainy), with dedicated adult and pediatric hematology services and an institutional import workflow; Ain Shams University Hospitals, with strong adult hematology and routine imported-specialty-drug experience; Dar Al Fouad Hospital in 6th of October City, with over 250 bone marrow transplants of operational experience; and the National Cancer Institute of Cairo University.

For families outside Cairo and Giza with a pediatric KMT2A-rearranged ALL or AML diagnosis, the practical pattern is referral to 57357 for case management, with the dispensing facility licence and the EDA filing held at 57357. Adult cases route to Kasr Al Ainy, Ain Shams, or the National Cancer Institute, with co-management from the regional hematologist where applicable.

Real cost picture for Revuforj 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. Per Syndax public disclosures, the US wholesale acquisition cost for Revuforj is approximately USD 39,500 per month at adult target dose, with the annualised order-of-magnitude reference at approximately USD 474,000 per patient per year. WAC excludes rebates, discounts, and US-only assistance programs. Pediatric weight-based dosing (160 mg/m² twice daily for patients under 40 kg) results in lower monthly drug consumption and lower per-month drug cost.

The drug cost is the dominant line item. International logistics for an oral room-temperature product are materially simpler and cheaper than for biologics; standard international air courier with declared-value insurance typically runs USD 200 to 500 per shipment. EDA permit fees and Egyptian customs charges sit on the dispensing facility's side. Hospital-side costs (oncologist consultation, CBC and chemistry monitoring, weekly ECG in the first month and monthly thereafter, differentiation syndrome surveillance, and any cytogenetic or molecular reassessment) are typically lower than for inpatient biologic regimens. 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 oncology imports case by case, with pre-authorisation typical for oral oncology of this unit cost. UHIA coverage of specialty oncology imports is not the operating path in 2026 for most patients. Cash-pay remains the dominant posture, with many Egyptian families coordinating USD funds from relatives in the Gulf.

Typical timeline for Revuforj in Egypt

For a routine Egyptian Revuforj case with complete molecular confirmation and physician documentation, the EDA personal-import window is typically 3 to 6 weeks. Because Revuforj is solid oral with room-temperature stability, there is no cold-chain transit-condition risk and no compounding step at the destination. Transit timing is governed by route documentation and destination-country pre-clearance, not by stability. A first-time import at a given Egyptian hematology centre may add 1 to 2 weeks for institutional pharmacy onboarding, though 57357 and Kasr Al Ainy both have well-established specialty import workflows that move on the faster end. Continuous twice-daily dosing means Reserve Meds plans repeat-shipment cadence (typically monthly or quarterly) at case acceptance rather than treating each shipment as a one-off.

What your physician needs to provide

The clinical justification letter is the cornerstone of the EDA application and, for Revuforj, the strongest letters consistently include: confirmed diagnosis of acute leukemia (AML or ALL) with the cytogenetic or molecular report demonstrating KMT2A translocation (KMT2Ar) or, for AML, a susceptible NPM1 mutation; the disease state (relapsed or refractory after prior therapy) per the FDA-approved indication; the full prior-therapy sequence including induction, consolidation, and salvage attempts; the proposed dosing plan with patient weight and body surface area (270 mg orally twice daily for patients 40 kg or more; 160 mg/m² orally twice daily for patients under 40 kg), with CYP3A4 inhibitor dose adjustment noted if applicable; the differentiation syndrome surveillance plan for the first 28 days; the ECG and electrolyte monitoring plan; the concomitant medication review (particularly for azole antifungal prophylaxis common in acute leukemia); and the prescribing physician's EMS membership and Ministry of Health licence verification matched to the dispensing facility.

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 direct dosing, and do not file adverse-event reports.

Common questions about Revuforj in Egypt

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

Each insurer assesses named-patient oncology imports case by case, with pre-authorisation typical at this unit cost. Reserve Meds supplies the documentation set; the claim filing stays with you or the dispensing hospital. Cash-pay remains the dominant posture and many Egyptian families reimburse themselves later if coverage applies.

Is Revuforj eligible for our pediatric patient?

Yes, from age 1 year and older with confirmed KMT2A translocation (any leukemia subtype) or, for AML, a susceptible NPM1 mutation. Pediatric eligibility from age 1 is unusual for a novel targeted oncology agent and is one of the reasons 57357 is a natural Egyptian dispensing centre for pediatric KMT2Ar cases. Pediatric dosing is body-surface-area based at 160 mg/m² twice daily for patients under 40 kg.

What is the safety profile we should monitor?

The FDA label carries a boxed warning for differentiation syndrome, which can be fatal. Other notable risks include QT-interval prolongation, embryo-fetal toxicity, and myelosuppression. In the AUGMENT-101 KMT2Ar cohort, grade 3 or higher febrile neutropenia occurred in 37.2 percent, differentiation syndrome in 16.0 percent, and QTc prolongation in 13.8 percent of treated patients. Mandatory monitoring includes differentiation syndrome surveillance in the first 28 days and weekly ECGs in the first month, monthly thereafter, with electrolyte (potassium, magnesium) correction.

Is there an alternative to Revuforj?

There is no approved competitor in the menin-inhibitor class as of this review. Other menin inhibitors (for example ziftomenib) are in clinical development but not approved. Outside the menin-inhibitor class, standard relapsed or refractory acute-leukemia regimens are mechanistically different and do not target the menin-KMT2A interaction. Comparative selection is a treating-physician decision.

What is the typical course duration?

Dosing is continuous, twice daily, until disease progression or unacceptable toxicity. There is no fixed end point. In responders, the AUGMENT-101 median duration of complete remission (with or without full hematologic recovery) was 6.4 months in the KMT2Ar cohort. Many responders subsequently proceed to allogeneic hematopoietic stem cell transplant. Planning for multi-month continuous supply is the working assumption.

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 Revuforj cases

Reserve Meds is a US-based concierge coordinator. We do not replace your hematologist or pediatric oncologist, do not replace EDA, and do not act as an Egyptian importer of record. What we do is orchestrate the US-side sourcing through Syndax-authorized specialty pharmacy partners with DSCSA serialization and full pedigree, prepare the international logistics, and assemble the documentation kit your physician needs for the EDA Personal Importation filing. Because

Revuforj is continuous oral therapy on a multi-month course, Reserve Meds plans repeat-shipment cadence at case acceptance and stays on the case through subsequent re-supply. Revuforj has no prior Reserve Meds case experience as of this review, so the operating posture is standard NPP coordination with particular attention to molecular-confirmation documentation, pediatric weight-band dosing, and the concomitant CYP3A4 inhibitor review.

Next step

If an adult or pediatric family member in Egypt has relapsed or refractory acute leukemia with confirmed KMT2A translocation or, for AML, a susceptible NPM1 mutation, and the treating hematologist or pediatric oncologist is considering Revuforj, 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; Reserve Meds is the coordinator, not the prescriber.