Revuforj access in Saudi Arabia via the SFDA named-patient pathway

How patients in the Kingdom of Saudi Arabia obtain Revuforj (revumenib) for relapsed or refractory KMT2A-rearranged or NPM1-mutated acute leukemia, through the Saudi Food and Drug Authority Personal Importation Program.

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

1. Quick orientation

Revuforj is the brand name for revumenib, a first-in-class oral small-molecule menin inhibitor developed by Syndax Pharmaceuticals. The US Food and Drug Administration granted accelerated approval on November 15, 2024 for relapsed or refractory acute leukemia with a KMT2A translocation in adult and pediatric patients 1 year of age and older. In October 2025, the FDA expanded the label to include relapsed or refractory acute myeloid leukemia with a susceptible NPM1 mutation in patients 1 year of age and older. For families in Saudi Arabia with a molecularly defined relapsed or refractory acute leukemia and a treating hematologist-oncologist who has identified Revuforj as the right next-line therapy, the Saudi Food and Drug Authority (SFDA) Personal Importation Program (PIP) is the lawful, documented route. Reserve Meds is the US-side coordinator that aligns the sourcing, the documentation kit, and the international logistics. Reserved for you.

2. Why patients in Saudi Arabia need Revuforj via NPP

Three features combine to make Revuforj a high-fit named-patient candidate in the international acute-leukemia population. First, KMT2A-rearranged acute leukemia is rare. It accounts for a small minority of adult AML and a slightly larger fraction of infant and pediatric ALL. The absolute patient count in any individual ex-US market is small, which discourages local stocking and slows the regulatory ROI calculation for a manufacturer to register country by country. SFDA has no public registration record for Revuforj as of the review date. Second, Revuforj is first-in-class. No other menin inhibitor is approved, and no generic exists. There is no therapeutically equivalent local substitute that a Saudi hematologist-oncologist can prescribe instead. Third, the pediatric eligibility (age 1 year and older) at first approval is unusual for a novel targeted oncology therapy, which expands the legitimate cross-border request pool to infant and pediatric KMT2Ar leukemia cases routinely seen at KFSH&RC and similar tertiary pediatric oncology programs.

The unmet need is intense and the molecular gating is specific. A relapsed or refractory acute leukemia patient in Riyadh, Jeddah, or the Eastern Province with a confirmed KMT2A translocation or a susceptible NPM1 mutation has no class-equivalent alternative locally registered. Standard relapsed or refractory regimens are mechanistically different and are not selected for KMT2A or NPM1 biology.

Reserve Meds positions Revuforj as a Tier-1 access case where the operational profile is unusually favorable on the logistics side (room-temperature oral tablets, no cold chain, no compounding) and unusually demanding on the documentation side (molecular confirmation evidence, pediatric weight-band dosing documentation where applicable, and CYP3A4 interaction planning).

3. The SFDA Personal Importation Program for Revuforj

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 Revuforj) and a clinically equivalent locally registered alternative is not suitable. The framework explicitly contemplates oncology, pediatric specialty, 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 Revuforj specifically, the application package contains:

- **Clinical justification letter** from the treating hematologist-oncologist, addressing diagnosis with ICD-10 coding (C92.x for AML or C91.x for ALL subtypes), relapsed or refractory status with the prior-line therapy history, the molecular confirmation (KMT2A rearrangement by FISH, conventional karyotype, or molecular testing, or NPM1 mutation by sequencing) with the laboratory report referenced, and the rationale for menin inhibition in this clinical setting.
- **SCFHS licensure verification** in hematology, oncology, or pediatric hematology-oncology, as the patient's case requires.
- **Molecular confirmation evidence.** The KMT2A or NPM1 confirmation laboratory report must accompany the file. This is the FDA-labeled gating criterion and the most likely point of SFDA query if the file is incomplete.
- **Differentiation syndrome surveillance plan.** The FDA label carries a boxed warning for differentiation syndrome, and surveillance is mandatory during the first 28 days of treatment. The PIP file should reflect that this monitoring is in place at the destination institution, including readiness to initiate corticosteroid therapy and hemodynamic monitoring if differentiation syndrome is suspected.
- **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 (Revuforj), international nonproprietary name (revumenib), manufacturer (Syndax Pharmaceuticals, Inc.), country of origin (USA), strength (110 mg or 160 mg film-coated tablet), pack size, requested quantity for the initial sourcing window, lot, and expiry.
- **Destination dispensing facility license** showing the receiving hospital or oncology pharmacy is SFDA-licensed to handle imported oral oncology agents.
- **Chain-of-custody plan** from the US specialty pharmacy through international transit (standard air courier with declared-value insurance; no cold chain required) 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. First-time imports of a launch-phase targeted oncology therapy can extend toward the 6 to 10 week range while internal pharmacy committees and the importer onboard a new product. SFDA does not publish guaranteed turnaround times.

4. Where Revuforj gets dispensed in Saudi Arabia

Revuforj is a room-temperature oral tablet, so the storage and shipping footprint is simpler than for the biologics and cell therapies that dominate the oncology NPP request mix. The institutions in Saudi Arabia with the hematology-oncology coverage, the molecular pathology infrastructure to confirm KMT2A rearrangement or NPM1 mutation, the differentiation syndrome monitoring capacity, and the import pharmacy workflow to handle Revuforj 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 in Riyadh and Jeddah; 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. KFSH&RC's pediatric oncology and bone marrow transplant programs are the natural fit for infant and pediatric KMT2Ar leukemia cases.

Smaller hospitals without internal import pharmacy capacity typically route Revuforj cases through one of these centers, or through an SFDA-licensed specialty importer based in Riyadh or Jeddah who handles the SFDA filing and the customs clearance under the destination facility's institutional license.

5. Real cost picture for Revuforj in Saudi Arabia

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

Drug acquisition. Per Syndax public WAC disclosures (state pricing transparency filings in Colorado and Vermont), the US wholesale acquisition cost for Revuforj is approximately USD 39,500 per month. On an annualized basis the order-of-magnitude reference is approximately USD 474,000 per patient per year at WAC, which translates to roughly SAR 1.78 million annualized at the WAC reference. Patient-level cost varies with weight-band dosing (270 mg twice daily for patients 40 kg and over, weight-based for smaller patients) and with CYP3A4 inhibitor co-administration (dose reduction to 160 mg twice daily for patients 40 kg and over on strong CYP3A4 inhibitors such as azole antifungals).

International logistics surcharge. Standard international air courier with declared-value insurance and customs documentation, plus importer-of-record handling, typically adds SAR 1,500 to SAR 5,000 per shipment. Because Revuforj is room-temperature and stable, transit-condition risk is among the lowest in the oncology category, and shipment cadence can be consolidated more flexibly than for cold-chain biologics.

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 molecular-confirmation review), US sourcing through Syndax-authorized specialty channels, customs paperwork, and a single named coordinator from intake through reorders.

Local hematology-oncology visits, molecular confirmation testing, ECG monitoring at baseline and weekly for the first month then at least monthly thereafter, electrolyte monitoring (potassium, magnesium) for QT prolongation mitigation, CBC and chemistry monitoring, and physician oversight are billed by the receiving Saudi institution and are not part of the Reserve Meds quote. Local insurer behavior 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 Revuforj in Saudi Arabia

From the date the clinical justification letter and the molecular confirmation report are submitted, routine SFDA review for Revuforj typically runs 10 to 21 business days. First-time imports of a launch-phase targeted oncology therapy at an institution can extend toward the 6 to 10 week range. Because Revuforj is room-temperature and shipped via standard international air courier, transit adds 2 to 5 business days rather than the longer windows associated with validated cold-chain logistics. Therapy is continuous twice-daily oral dosing rather than cycled IV infusion, so the reorder cadence is monthly rather than every two or three weeks. Reserve Meds plans multi-month sourcing at case acceptance to avoid any gap in continuous dosing.

7. What your physician needs to provide

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

- **Diagnosis and molecular characterization.** Histologically confirmed acute leukemia, with the molecular driver documented as either a KMT2A translocation (by FISH, conventional karyotype, or molecular testing) or a susceptible NPM1 mutation (by sequencing). The laboratory report is referenced and attached.
- **Prior-line documentation.** Relapsed or refractory status after the prior regimen or regimens, with start and stop dates and the date and pattern of progression.
- **Mechanism rationale.** Why menin inhibition is appropriate for this KMT2A-rearranged or NPM1-mutated leukemia, in line with the FDA-labeled indication.

- **Dosing plan.** For patients 40 kg or more, 270 mg orally twice daily (or 160 mg twice daily when co-administered with a strong CYP3A4 inhibitor such as posaconazole or voriconazole). For patients less than 40 kg, 160 mg/m² orally twice daily (or 95 mg/m² twice daily on strong CYP3A4 inhibitors). Tablets taken approximately 12 hours apart with or without food.
- **Monitoring plan.** Differentiation syndrome surveillance during the first 28 days, with clinical monitoring for fever, dyspnea, hypotension, pulmonary infiltrates, peripheral edema, and rapid leukocytosis, and readiness to initiate corticosteroid therapy and hemodynamic support immediately if suspected. ECG at baseline, weekly for the first month, and at least monthly thereafter, with potassium and magnesium correction to mitigate QT prolongation. Standard CBC and chemistry monitoring.
- **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, so the physician is not building the file from scratch.

8. Common questions about Revuforj in Saudi Arabia

Will Bupa Arabia, Tawuniya, or MedGulf cover Revuforj? Each plan handles named-patient imports case-by-case under CCHI rules. Pre-authorization is typically required for a targeted oncology agent at this price point, and reimbursement, where available, often comes after the fact through the patient's own claim. Cash-pay is the default operating posture.

Does Revuforj work for both adults and pediatric patients? Yes. The FDA label covers patients 1 year of age and older, with weight-based dosing for patients under 40 kg and a fixed dose for patients 40 kg and over. KFSH&RC and other tertiary pediatric oncology centers in KSA are appropriate sites for pediatric KMT2Ar leukemia cases.

What about CYP3A4 interactions? Co-administration with a strong CYP3A4 inhibitor (which is clinically common in this patient population because azole antifungals such as posaconazole or voriconazole are frequently used for invasive fungal prophylaxis) requires dose reduction per the FDA label. The dosing plan in the clinical justification letter should reflect whether the patient is on a strong CYP3A4 inhibitor and what the adjusted dose is.

What is the safety profile? 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.

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 proceeded to allogeneic hematopoietic stem cell transplant. Planning for multi-month continuous supply is the working assumption.

Is there a comparator? There is no approved competitor in the menin-inhibitor class. Outside the menin-inhibitor class, standard relapsed or refractory acute-leukemia options operate via different mechanisms and are not selected for KMT2A or NPM1 biology. The decision belongs with the treating hematologist-oncologist.

9. Where Reserve Meds fits in Revuforj cases

Reserve Meds has no prior Saudi Revuforj case experience as of the review date. Standard NPP coordination applies, with two operating notes specific to this product: molecular confirmation review at intake (the KMT2A or NPM1 laboratory report is reviewed before the documentation kit is sent, because this is the FDA-labeled gating criterion and the most likely point of SFDA query); and multi-month continuous supply planning at case acceptance, given the twice-daily continuous oral dosing and the open-ended treatment duration. The clinical decisions remain with the SCFHS-licensed hematologist-

oncologist. The regulatory authority remains SFDA. The dispensing remains with the licensed Saudi pharmacy. Reserve Meds is the connective tissue between the US specialty pharmacy and those three Saudi pillars.

10. Next step

If your treating hematologist-oncologist in Saudi Arabia has identified Revuforj as the right next-line therapy for a confirmed KMT2A-rearranged or NPM1-mutated acute leukemia, the next step is to add your case to the waitlist so Reserve Meds can confirm eligibility within 24 to 48 hours, review the molecular confirmation report, and send the documentation kit to your physician.

Reserved for you.

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