Mektovi access in the Kingdom of Saudi Arabia

How families in the Kingdom pursue Mektovi (binimetinib), Pfizer's MEK1 and MEK2 inhibitor, through the SFDA Personal Importation Program.

Last reviewed 2026-05-12 by Reserve Meds clinical & regulatory team. This page combines the Saudi Arabia country research module with the Mektovi drug module to describe the path families actually walk.

Quick orientation

Mektovi (binimetinib) is Pfizer's MEK inhibitor, used in combination with encorafenib (Braftovi) for BRAF V600E or V600K mutation-positive metastatic melanoma and for BRAF V600E mutation-positive metastatic non-small cell lung cancer. It received FDA approval in 2018 for melanoma and added the NSCLC indication in 2023. For Saudi Arabia patients with a confirmed BRAF V600 mutation and a treating oncologist's recommendation for the encorafenib-plus-binimetinib regimen, this page describes the SFDA Personal Importation Program pathway. The manufacturer attribution for Mektovi has shifted across acquisitions (originally Array BioPharma, then Pfizer); regional distribution arrangements vary by country and are documented in the PIP file as appropriate.

Why this drug is hard to source in Saudi Arabia

BRAF V600 mutation-positive melanoma and NSCLC are well-defined patient populations, and SFDA registration for the encorafenib-plus-binimetinib regimen has progressed in the GCC. The access gap typically presents as stock interruption at the dispensing pharmacy or as a new indication (NSCLC) where the local label has not been updated to match the FDA label. Both drugs in the combination must be present, so a stockout of either binimetinib or encorafenib breaks the regimen. The PIP route lets the treating oncologist bridge the gap for a named patient.

The SFDA Patient Import Permit (PIP) pathway applied to Mektovi

The Saudi Food and Drug Authority's Personal Importation Program is the federal pathway that allows an SCFHS-licensed physician to import a specific medicine for a specific named

patient when the medicine is approved by a recognized reference authority (typically the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable. Mektovi (binimetinib) holds FDA approval since 2018 for BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma in combination with encorafenib (Braftovi); and BRAF V600E mutation-positive metastatic non-small cell lung cancer in combination with encorafenib, which places it squarely within the framework's scope.

The application is filed through the dispensing institution's import pharmacy (or, where the institution does not hold internal import-pharmacy capability, through an SFDA-licensed specialty importer in Riyadh or Jeddah). The standard package contains the clinical justification letter from the treating physician, the SCFHS license verification, the anonymized patient identifier, the full product details for Mektovi including 15 mg oral tablet, twice-daily dosing (45 mg twice daily standard), an ambient-temperature product, the destination dispensing facility license, and the chain-of-custody plan from the US point of release through international transit to the receiving Saudi pharmacy. The SFDA portal at sfda.gov.sa handles regulatory transactions, and named-patient activity increasingly routes through the agency's Ghad digital platform.

Where Mektovi gets dispensed in the Kingdom

The major Saudi institutions that handle named-patient imports as established workflow include King Faisal Specialist Hospital and Research Centre (KFSH&RC) with operations in Riyadh, Jeddah, and Madinah; King Abdulaziz Medical City (KAMC) and the Ministry of National Guard Health Affairs network; King Saud University Medical City and the academic medical centers; King Khalid University Hospital; Dr. Sulaiman Al Habib Medical Group (HMG) across multiple Riyadh, Jeddah, and Eastern Province facilities; the Saudi German Hospital network; Dr. Soliman Fakeeh Hospital in Jeddah; and Dallah Hospital in Riyadh. Smaller hospitals typically route their named-patient cases through one of these centers or through an SFDA-licensed specialty importer. For a Mektovi case, the dispensing facility is selected on the basis of where the treating physician practices and where the patient receives ongoing care; Reserve Meds does not select the dispensing facility on the family's behalf.

Real costs in SAR and USD

The US wholesale acquisition cost for Mektovi alone is approximately USD 12,000 to USD 14,000 per 30-day supply (180 tablets at 15 mg), translating to roughly SAR 45,000 to SAR 52,500. The companion encorafenib (Braftovi) at standard dosing adds another approximately USD 14,000 to USD 16,000 per month. The combination cost is approximately SAR 97,500 to SAR 112,500 per month. International logistics for an ambient-temperature

oral oncology product add approximately SAR 1,500 to SAR 3,000 per shipment. Bupa Arabia, Tawuniya, and MedGulf each handle this regimen case by case.

Reserve Meds quotes an indicative range based on the initial intake and then a transparent firm quote with each line item shown separately. The Reserve Meds concierge fee is published on a tiered schedule and is shown as a separate line. Nothing is bundled. Nothing is hidden.

Timing, what to expect

The SFDA Personal Importation Program processes routine cases (recognized reference-authority drug, well-documented indication, established institution) in approximately 10 to 20 business days. Complex cases (novel mechanism, off-label use within the FDA label scope, ultra-rare patient population, first-time importer) can extend to 6 to 8 weeks. SFDA does not publish guaranteed turnaround times, so case-by-case planning is the norm. In parallel with the SFDA review, Reserve Meds aligns the US-side sourcing, the packaging and ambient-temperature shipping validation, and the shipment plan, so the drug is ready to move on the day approval comes through. The patient experience runs through ten well-defined steps from initial physician decision through reorder coordination; the full ten-step sequence is documented in the Saudi Arabia country module and in our patient-facing operations brief.

What your physician needs to provide

The treating oncologist's clinical justification letter typically documents the confirmed BRAF V600E or V600K mutation (molecular pathology report attached), the staging and disease setting (metastatic melanoma or metastatic BRAF V600E NSCLC), prior therapies if any, the rationale for the encorafenib-plus-binimetinib combination over single-agent BRAF inhibition or alternative regimens, the proposed dose (encorafenib 450 mg once daily plus binimetinib 45 mg twice daily standard), and the planned monitoring (left ventricular ejection fraction, ophthalmologic evaluation, liver enzymes, creatine kinase, dermatologic surveillance). The SCFHS registration in medical oncology accompanies the letter.

The dispensing facility's SFDA-licensed pharmacy completes the submission and accepts the chain-of-custody documentation. The institutional license is what authorizes the dispensing pharmacy to receive the imported drug, so the physician's individual SCFHS license is necessary but not sufficient on its own. Post-import pharmacovigilance commitment to report adverse events through the SFDA National Pharmacovigilance Center is part of the application and runs through the full course of therapy, not just the initial dose.

Vision 2030 and the specialty-access environment

Saudi Vision 2030's Health Sector Transformation Program (HSTP) is the operating frame for healthcare reform in the Kingdom. HSTP is restructuring the Ministry of Health from a provider-and-regulator into a regulator and strategist, with clinical delivery devolving into regional Health Clusters and Centers of Excellence. The program names tertiary cancer care, rare-disease care, organ transplantation, genomics, and digital health as priority verticals, all of which are heavy users of specialty drugs not registered locally. The practical effect on the PIP framework is twofold. HSTP is expanding the universe of specialty drugs that get formal SFDA registration, which closes some access gaps. At the same time, HSTP is increasing diagnostic capacity in rare disease and oncology genomics, which surfaces new patients who need drugs that are FDA-approved but not yet registered in the Kingdom. The named-patient framework remains essential for the foreseeable future. Saudization (the Nitaqat workforce-nationalization program) does not change the PIP framework, but confirming the prescriber's SCFHS license status before filing is good practice in any case where the treating physician is in a renewal window.

Pharmacovigilance and shipping considerations

The encorafenib-plus-binimetinib regimen carries warnings for cardiomyopathy and decreased left ventricular ejection fraction, venous thromboembolism, ocular toxicity including serous retinopathy and retinal vein occlusion, hepatotoxicity, rhabdomyolysis, hemorrhage, hypertension, dermatologic toxicity, and new primary malignancies. The SFDA pharmacovigilance commitment includes baseline and periodic LVEF assessment, ophthalmologic evaluation, liver enzyme monitoring, and any serious adverse event reporting. Cold-chain is not required.

Reserve Meds' physician documentation kit includes the SFDA adverse-event reporting reference so the treating physician has the framework on hand from day one. Reserve Meds does not file adverse-event reports; that responsibility sits with the SCFHS-licensed treating physician. The dispensing facility carries the chain-of-custody and storage obligations through the dispensing event, and off-label transfer of the imported supply to another patient is not permitted under the PIP framework.

Common questions about Mektovi in the Kingdom

Will Bupa Arabia, Tawuniya, or MedGulf cover this? Each insurer handles named-patient imports case by case under the Council of Cooperative Health Insurance (CCHI) framework. Some plans reimburse fully when the medicine appears on the insurer's formulary even where the local hospital pharmacy does not stock it. Others reimburse a percentage. Many require pre-authorization with the clinical justification letter attached. Reserve Meds

supplies the documentation that lets the insurer assess the case; the claim is yours or your hospital's to file. Cash-pay is the default operating posture for cross-border access, with reimbursement sought after delivery where your plan permits.

Will my Ministry of Health-employed physician's letter be sufficient if SFDA flags the case? Yes. KSA-licensed physicians at Ministry of Health hospitals, KFSH&RC, KAMC, MNGHA, KSUMC, and other public-sector institutions have full signing authority on PIP applications under their SCFHS license. The clinical justification letter is the cornerstone of the package. Private-sector physicians at HMG, Saudi German, Fakeeh, Dallah, and similar institutions also have signing authority under their institutional license.

Can I receive the drug at home, or do I need a hospital? The dispensing facility must be a locally licensed pharmacy. For oral medicines, a hospital outpatient pharmacy or specialized SFDA-licensed import pharmacy dispenses to the patient. For infusion or injection products, the medicine ships to the infusion center where you will receive it. Direct-to-home delivery without a licensed dispensing facility in the chain is not the operating model.

What about pediatric patients? The PIP framework applies to pediatric patients the same way it applies to adults. The clinical justification letter typically includes weight-based dosing, pediatric-specific monitoring, and where relevant the involvement of the pediatric specialty center. KFSH&RC, KAMC, and the major HMG facilities have established pediatric specialty programs that handle named-patient imports routinely.

How does Saudization (Nitaqat) affect my case? Saudization is the workforce-nationalization program that shapes hospital staffing composition. It does not change the PIP framework. It can occasionally affect timing if a non-Saudi treating physician's license is in renewal at the moment the PIP file is being prepared. Confirming the prescriber's SCFHS license status before filing is good practice.

Is Mektovi a controlled substance? No. Mektovi is not a US DEA scheduled substance. The Saudi narcotics-section approvals do not apply. The chain-of-custody documentation, the dispensing facility's pharmaceutical establishment license, and the SFDA pharmacovigilance commitment do apply.

Where Reserve Meds fits in Mektovi cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating physician, the SFDA, the dispensing pharmacy, or the institutional import-pharmacy team. For a Mektovi case in the Kingdom, our work is to orchestrate the US-side sourcing, prepare the regulatory documentation kit your physician needs, coordinate international logistics with ambient-temperature shipping validation where required, and assign a single named coordinator who stays with the case through reorders. The clinical decisions remain with the treating physician. The regulatory authority remains SFDA. The dispensing remains

with the licensed Saudi pharmacy. Reserve Meds is the connective tissue between the US supply side and those three Saudi pillars. Reserved for you.

Next step

If a treating physician in the Kingdom is weighing Mektovi for a patient, the waitlist is the first step. We respond within 24 to 48 hours with an eligibility confirmation and a documentation kit for the physician.

Reserved for you.

Related

- Mektovi clinical resource
- Mektovi in the United Arab Emirates
- Mektovi in Qatar
- Mektovi in Kuwait
- Kingdom of Saudi Arabia country page

Sources

1. FDA approval, Mektovi (binimetinib), Pfizer (acquired through the Array BioPharma acquisition; previously distributed by Pierre Fabre in some markets), initial FDA approval 2018.
2. Saudi Food and Drug Authority (SFDA), Personal Importation Program framework, https://www.sfda.gov.sa/en, and the Ghad digital regulatory platform at https://ghad.sfda.gov.sa/.
3. Saudi Vision 2030, Health Sector Transformation Program, https://www.vision2030.gov.sa/en/explore/programs/health-sector-transformation-program.
4. Saudi Commission for Health Specialties (SCFHS), https://scfhs.org.sa/en, for treating-physician licensing and the institutional pharmacy framework.

Review and oversight. Content on this page is reviewed by the Reserve Meds 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 ›
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