Braftovi

Saudi Arabia · access guide

How to access Braftovi for BRAF V600-mutant melanoma, colorectal cancer, and lung cancer from Saudi Arabia: 2026 pathway via Saudi medical oncology and the combination partner regimen

By Reserve Meds clinical & regulatory team. Last reviewed 2026-05-20.

Saudi Arabia has the deepest adult medical oncology and molecular diagnostics infrastructure in the Gulf. King Faisal Specialist Hospital and Research Centre (KFSHRC) in Riyadh and Jeddah, King Abdulaziz Medical City (KAMC) Riyadh, King Fahad Medical City (KFMC) Riyadh, Princess Noorah Oncology Centre Jeddah, and the Dr Sulaiman Al Habib oncology network all run medical, GI, thoracic, and dermato-oncology services that diagnose, biomarker-test, and treat BRAF V600-mutant melanoma, metastatic colorectal cancer, and non-small cell lung cancer (NSCLC). Braftovi (encorafenib) is registered with the Saudi Food and Drug Authority (SFDA) for the melanoma indication and is in routine prescribing at KFSHRC, KAMC, and KFMC. The colorectal and NSCLC indications are at various stages of SFDA file maturity in 2026; for the most recent of the three indications (NSCLC, FDA October 2023), the named-patient programme (NPP) pathway through the prescribing centre's regulatory office remains a frequent route. The Braftovi case is always a combination-therapy case: Braftovi plus binimetinib (Mektovi) for melanoma and NSCLC; Braftovi plus cetuximab (Erbitux) for colorectal cancer. The payer pre-authorisation conversation is always a two-drug conversation, never a single-drug conversation.

This page explains how the pathway works in 2026 for a Saudi-resident adult: who qualifies, where the diagnostic and molecular workup happens, where the prescriptions for both drugs are written and filled, what the realistic out-of-pocket exposure band is in SAR for the combined regimen, what to monitor on therapy (liver enzymes, cardiac function, ophthalmologic and dermatologic surveillance, QT interval), and how a multi-month combination-therapy course settles into a Saudi family's life. It is concierge documentation written for a family that is already in conversation with a treating medical oncologist and wants the operational reality of the combination regimen laid out plainly.

Why Braftovi, and why now

Braftovi is encorafenib, a highly selective, oral, ATP-competitive inhibitor of mutant BRAF V600E and V600K kinase. It was discovered at Novartis, developed and brought to first FDA approval by Array BioPharma, and acquired by Pfizer in June 2019 in the USD 11.4 billion Array transaction. The pharmacology point that distinguishes Braftovi from earlier BRAF inhibitors (vemurafenib, dabrafenib) is a substantially longer dissociation half-life from the kinase target, which translates into more sustained MAPK pathway inhibition at clinical doses. Braftovi is almost never given as monotherapy. The combination partner is indication-specific.

The three FDA approvals are:

- **Melanoma (June 2018)**: Braftovi 450 mg PO once daily plus binimetinib (Mektovi) 45 mg PO twice daily, for adults with BRAF V600E or V600K-mutant unresectable or metastatic melanoma. The pivotal data is the COLUMBUS trial (Lancet Oncology 2018): median progression-free survival 14.9 months on Braftovi plus Mektovi versus 7.3 months on vemurafenib monotherapy; median overall survival 33.6 months versus 16.9 months. This is the most established of the three indications in Saudi Arabia. KFSHRC Riyadh and Jeddah, KAMC, and KFMC use Braftovi plus Mektovi as a first-line option for confirmed BRAF V600E-mutant metastatic melanoma. - **Colorectal cancer (April 2020)**: Braftovi 300 mg PO once daily plus cetuximab (Erbitux) 400 mg per square metre IV loading dose then 250 mg per square metre IV weekly, for adults with BRAF V600E-mutant metastatic colorectal cancer after prior therapy. The pivotal data is the BEACON CRC trial (NEJM 2019, updated 2020): median overall survival 9.3 months on the doublet versus 5.9 months on standard-of-care chemotherapy. The combination doublet is the FDA-approved regimen. - **NSCLC (October 2023)**: Braftovi 450 mg PO once daily plus binimetinib 45 mg PO twice daily, for adults with BRAF V600E-mutant metastatic NSCLC. The pivotal data is the PHAROS trial (JCO 2023): objective response rate 75 percent in treatment-naive patients and 46 percent in pre-treated patients. This is the most recent of the three indications and the one most likely to run via NPP pathway in mid-2026 where the SFDA file may lag the FDA October 2023 timing. [VERIFY: current SFDA label scope across the three indications]

For a Saudi patient with confirmed BRAF V600E or V600K-mutant metastatic melanoma, the Braftovi plus Mektovi combination sits as one of three FDA-approved BRAF plus MEK doublets (alongside dabrafenib plus trametinib and vemurafenib plus cobimetinib). Choice between the three combinations is largely a tolerability and physician-familiarity decision in 2026 Saudi practice. For confirmed BRAF V600E metastatic CRC, the Braftovi plus cetuximab doublet is the standard-of-care for the BRAF V600E-mutant subset after prior chemotherapy. For confirmed BRAF V600E NSCLC, the Braftovi plus Mektovi combination is the most recent targeted option.

What Braftovi is, in plain language

Braftovi is an oral 75 mg capsule. The dose depends on indication: six capsules once daily (450 mg total) for melanoma and NSCLC; four capsules once daily (300 mg total) for colorectal cancer. Taken with food. Storage is room temperature. There is no infusion of Braftovi itself.

The combination partner depends on indication:

- **For melanoma and NSCLC**: binimetinib (Mektovi), an oral 15 mg tablet. The patient takes Mektovi 45 mg twice daily (three 15 mg tablets per dose, six tablets per day total). Approximately 12 hours between doses. Taken with or without food. - **For colorectal cancer**: cetuximab (Erbitux), a chimeric monoclonal antibody administered as a weekly IV infusion at the prescribing centre's infusion suite. The first dose is 400 mg per square metre body surface area infused over approximately 2 hours; subsequent weekly doses are 250 mg per square metre over approximately 1 hour. The cetuximab schedule is the operational anchor for the CRC regimen.

For the melanoma and NSCLC indications, the patient takes both drugs at home and visits the prescribing centre for monitoring labs and imaging on the standard outpatient cadence. For the CRC indication, the patient comes to the infusion centre once a week for cetuximab while taking Braftovi at home daily. The clinical pathway from first prescription to ongoing refill is the standard adult medical oncology shape, with the additional discipline of two-drug pre-authorisation and synchronised dispensing.

The mechanism, in clinical shorthand: BRAF V600E or V600K mutation produces a constitutively active mutant BRAF kinase that drives MAPK signalling (BRAF to MEK to ERK) independently of normal upstream RAS regulation. Braftovi binds the mutant BRAF kinase ATP pocket with high selectivity and has a longer target residence time than earlier BRAF inhibitors, sustaining pathway inhibition. Adding a MEK inhibitor (binimetinib) downstream blocks the paradoxical pathway activation in BRAF wild-type cells that drives the keratoacanthoma and cutaneous squamous cell carcinoma signal of BRAF monotherapy, and improves overall survival relative to BRAF monotherapy. Adding an anti-EGFR antibody (cetuximab) in BRAF V600E-mutant colorectal cancer blocks an upstream feedback loop that limits BRAF inhibitor efficacy in CRC histology specifically.

The biomarker requirement: confirmed BRAF V600E or V600K

Braftovi is a targeted therapy. It does not work on BRAF wild-type disease, and prescribing it without confirmed BRAF V600 positivity is not appropriate. The eligibility gate is the molecular diagnostic confirmation.

BRAF V600 mutation is detected by one or more of:

- **Next-generation sequencing (NGS) on tumour tissue**: the preferred test in 2026 across all three indications. NGS detects BRAF V600E (most common), V600K (melanoma; uncommon in CRC and NSCLC), and other less common BRAF variants. NGS panels typically also report KRAS, NRAS, and other relevant biomarkers in a single workup, which matters for the CRC indication where RAS status determines cetuximab eligibility. - **PCR-based BRAF mutation assay** (cobas BRAF V600 Mutation Test or equivalent): detects V600E and V600K and remains in routine use at many Saudi pathology services. - **Immunohistochemistry (IHC) with VE1 antibody**: a screening tool that detects BRAF V600E protein expression. Positive IHC is generally sufficient to start treatment but is typically confirmed by NGS or PCR where the molecular detail informs later-line decisions.

Saudi-side molecular diagnostic capability sits at KFSHRC molecular pathology in Riyadh and Jeddah (one of the most established NGS programmes in the region), at KAMC molecular pathology, at KFMC molecular pathology, and at regional and international reference laboratories (Caris Life Sciences, Foundation Medicine) for complex panels and liquid biopsy work. If the original diagnostic biopsy did not include BRAF testing, the conversation often starts with submission of archived tissue to a reference lab or with re-biopsy. This is normal in 2026 and not a process delay.

Eligibility at a Saudi oncologist's clinic

For Saudi-resident patients, the medical oncology service applies the FDA, EMA, and major-guideline criteria for the relevant indication:

1. Histologically confirmed cancer matching one of the three indications (cutaneous melanoma, metastatic colorectal adenocarcinoma, or metastatic NSCLC). 2. Confirmed BRAF V600E or V600K mutation by NGS, PCR, or IHC. 3. For metastatic CRC: documented KRAS and NRAS wild-type status (cetuximab is not appropriate for RAS-mutant disease). 4. Staging workup with contrast CT, PET-CT where indicated, and brain MRI. CNS staging is part of baseline because BRAF V600-mutant cancers carry a high CNS-metastasis risk. 5. Baseline laboratory workup: complete blood count, comprehensive metabolic panel including LFTs and bilirubin, serum creatinine, fasting glucose, lipid panel. 6. Baseline ECG with QTc documentation. Braftovi can prolong the QT interval. 7. Baseline ophthalmologic examination including slit-lamp and dilated funduscopic exam. Uveitis is a recognised class effect of the BRAF plus MEK combinations. 8. Baseline echocardiogram with left ventricular ejection fraction. Mektovi can cause left ventricular dysfunction. 9. Baseline dermatology examination. Keratoacanthomas and cutaneous squamous cell carcinomas are a class effect of BRAF inhibitors; the prescribing centre's dermatology service is looped in for ongoing surveillance every 8 weeks during treatment. 10. Pregnancy and lactation screen. Braftovi and the combination partners are contraindicated in pregnancy. Effective contraception is required during treatment and for at least 2 weeks after the last dose of Braftovi (longer per the Mektovi or cetuximab partner label). 11. Drug interaction screen. Braftovi is metabolised by CYP3A4; strong inhibitors (clarithromycin, ketoconazole, ritonavir) and inducers (rifampin, phenytoin, St John's wort) modify exposure. Grapefruit and grapefruit juice are avoided.

A Saudi patient should arrive at the oncology conversation with the most recent diagnostic workup: pathology report with histology and BRAF biomarker results (plus RAS status if CRC), contrast CT or PET-CT, brain MRI, and the full treatment history with response and tolerability data if any prior systemic therapy has been given. Reserve Meds organises this documentation pack so the oncology team can confirm eligibility on the first review.

The Saudi prescribing and dispense picture, plainly

In 2026 the Saudi oncology centres with active Braftovi prescribing and refill experience include:

- King Faisal Specialist Hospital and Research Centre (KFSHRC) Riyadh: the national reference centre for adult oncology with comprehensive medical oncology, melanoma, GI, and thoracic services, an active molecular tumour board, and one of the deepest NGS programmes in the region. - KFSHRC Jeddah: the western-region counterpart with parallel oncology and molecular diagnostic capability. - King Abdulaziz Medical City (KAMC) Riyadh: a Ministry of National Guard Health Affairs flagship with medical oncology and a tumour board that reviews BRAF V600-positive cases. - King Fahad Medical City (KFMC) Riyadh: Ministry of Health flagship with medical oncology services. - Princess Noorah Oncology Centre Jeddah: a Ministry of National Guard Health Affairs western-region oncology centre. - Dr Sulaiman Al Habib Medical Group oncology network: a private-sector chain with medical oncology services across Riyadh, Jeddah, and Khobar.

The pathway:

1. **Diagnosis and molecular confirmation**: typically done at the diagnosing centre's pathology lab, at KFSHRC molecular pathology, or sent to a regional or international reference lab. Turnaround for BRAF V600 IHC is 3 to 7 days; PCR-based BRAF assays add another few days; NGS panels typically take 2 to 4 weeks. For CRC, RAS status is part of the same workup or is already documented from prior treatment lines. 2. **Multidisciplinary tumour board review**: KFSHRC, KAMC, and KFMC each run a melanoma, GI, or thoracic tumour board (and a molecular tumour board) that documents the BRAF V600-positive rationale, the combination partner choice (Mektovi or cetuximab), and the treatment plan. 3. **Insurance pre-authorisation for both drugs**: most Saudi private insurers (Bupa Arabia, Tawuniya, MEDGulf, Allianz Saudi Fransi) require documented BRAF V600 status, MDT recommendation, and a clinical rationale letter from the prescribing oncologist for both Braftovi and the combination partner. The pre-authorisation conversation is always a two-drug conversation. For Saudi nationals at KFSHRC, KAMC, and KFMC, the institutional formulary handles the BRAF V600-positive cases on the standard pathway without commercial insurance friction. Pre-authorisation typically takes 7 to 14 days for a complete file in the private-sector setting. 4. **NPP / named-patient pathway where indicated**: for the NSCLC indication (FDA October 2023), the SFDA file may lag the FDA timing in mid-2026. Where standard commercial supply is not yet available, the prescribing centre's regulatory office files the NPP request with the SFDA and coordinates with the Pfizer regional office for supply. Reserve Meds supports the documentation pack assembly and the regulatory liaison. 5. **Pharmacy dispense, synchronised across both drugs**: KFSHRC, KAMC, and KFMC hospital pharmacies fill both drugs together for institutional patients. For private-sector patients, the prescribing centre's pharmacy or a partnered specialty pharmacy fills both drugs on a 30-day or 60-day refill cycle. For the CRC combination, Braftovi is dispensed on a 30-day refill cycle and cetuximab is administered weekly at the prescribing centre's infusion suite. 6. **Refill cycle**: monthly thereafter for as long as the patient is on treatment. Continued dispensing requires documentation of ongoing monitoring labs, dermatology and ophthalmology surveillance, and treatment response.

Cost expectation in SAR

The cost framing for Braftovi is always a combination cost. The Braftovi-alone figure is a partial number; the patient and family see the combined drug spend each month.

For the **melanoma and NSCLC indications** (Braftovi 450 mg plus Mektovi 45 mg twice daily): US list price for Braftovi at the 450 mg once-daily dose is approximately USD 13,500 per 30-day supply; Mektovi adds approximately USD 13,000 to USD 14,000 per 30-day supply. Combined regimen US list price is approximately USD 25,000 to USD 30,000 per month, with an annual combined cost of approximately USD 300,000 to USD 360,000. At indicative 2026 cross rates, a single 30-day combined regimen at USD 27,500 is approximately SAR 103,000, and the annual combined cost at USD 330,000 is approximately SAR 1.24 million.

For the **colorectal cancer indication** (Braftovi 300 mg plus cetuximab IV weekly): US list price for Braftovi at the 300 mg once-daily dose is approximately USD 9,500 per 30-day supply; cetuximab at the standard weekly dose for a typical adult body surface area (1.7 to 1.9 square metres) is approximately USD 15,000 to USD 20,000 per month depending on body size and infusion schedule. Combined regimen US list price is approximately USD 25,000 to USD 35,000 per month, with an annual combined cost of approximately USD 300,000 to USD 420,000. At indicative 2026 cross rates, a single 30-day combined regimen at USD 28,000 is approximately SAR 105,000, and the annual combined cost at USD 350,000 is approximately SAR 1.31 million.

Total cost of care additions include the oncologist's consultation fees (monthly for melanoma and NSCLC; weekly during the cetuximab phase for CRC), monitoring laboratory fees (every 2 weeks for the first 6 months then monthly), imaging fees (contrast CT or PET-CT every 8 to 12 weeks, brain MRI every 12 weeks if CNS metastases at baseline), dermatology surveillance every 8 weeks, ophthalmology visits at 1 month then every 6 months, cardiac echocardiograms every 2 to 3 months, and for CRC the weekly infusion centre fees and IV cetuximab nursing. These add 8 to 18 percent to the combined drug cost base in Saudi private-sector settings. For Saudi nationals at KFSHRC, KAMC, and KFMC, institutional financial pathways apply.

Monitoring on therapy

The monitoring schedule for a Braftovi-containing combination is structured around the principal toxicities of both drugs:

- **Liver function tests**: every 2 weeks for the first 6 months, then monthly. AST and ALT elevations require dose interruption per protocol at grade 3 or higher. - **CBC**: every 2 to 4 weeks for the first 3 months, then monthly. Anaemia and cytopenias are recognised on the combination. - **ECG with QTc**: baseline, at 2 weeks, at 1 month, then as clinically indicated. Symptomatic QT prolongation is uncommon but recognised. - **Cardiac function (LVEF)**: baseline, at 1 month, then every 2 to 3 months on the Mektovi-containing combinations (melanoma and NSCLC). New LVEF reduction warrants dose interruption per protocol. - **Ophthalmology**: at 1 month, then every 6 months or symptom-driven on the Mektovi-containing combinations. Any new visual symptom (blurred vision, photopsia, scotoma) prompts urgent ophthalmology input to evaluate for uveitis or serous retinopathy. - **Skin surveillance**: dermatology review every 8 weeks during treatment to evaluate for keratoacanthomas and cutaneous squamous cell carcinomas. The signal is less prominent on Braftovi than on monotherapy BRAF inhibitors but is real, and the Saudi UV-intense climate adds to the salience of sun-protection counselling. - **For the cetuximab partner (CRC)**: weekly infusion with infusion-reaction watch, magnesium replacement for hypomagnesaemia, and acneiform rash management. - **Disease assessment**: contrast CT or PET-CT every 8 to 12 weeks; brain MRI every 12 weeks if CNS metastases at baseline.

Religious, ethical, and family-logistics framing

Braftovi and Mektovi are oral small molecules. They contain no animal-source material in standard manufacturing, no donor cells, no blood product. For these components, halal acceptability is not in question. Cetuximab, the CRC combination partner, is a chimeric monoclonal antibody manufactured in mammalian cell culture (SP2/0 mouse myeloma cell line); the classical Islamic jurisprudential framework for life-threatening illness already endorses the use of monoclonal antibodies and other biologics for chronic life-threatening conditions, and the question is settled in routine Saudi oncology practice at KFSHRC, KAMC, and KFMC. The treatment shape sits within the standard cultural framework.

The family-logistics burden of a Braftovi-containing combination sits in the chronicity, the pill count, and the discipline. For melanoma and NSCLC: six Braftovi capsules once daily plus four Mektovi tablets across two doses twelve hours apart, with monitoring labs every two weeks for the first six months, dermatology every eight weeks, ophthalmology and cardiac echocardiogram on the cadence above. The total daily pill count is ten tablets across two combined drugs. Adherence support (medication diary, pill organiser, smartphone reminders, family member co-monitoring) is part of the practical handoff at first dispense. For colorectal cancer: four Braftovi capsules once daily plus a weekly trip to the infusion centre for cetuximab, with cetuximab-specific monitoring (infusion reaction watch, magnesium replacement, acneiform rash management). The weekly clinic visit is the structural anchor for the CRC family schedule.

For working patients, the schedule is manageable but heavier than a single-drug regimen. Monitoring lab visits cluster well around standard workweek patterns. For CRC patients, the weekly infusion is the main calendar disruption and most Saudi centres offer scheduled morning slots that allow same-day return to work. Pregnancy and contraception requirements are real for younger patients and the conversation needs to happen before the first prescription. For Saudi family arrangements, the option of inpatient oncology day-care at KFSHRC or KAMC for the weekly cetuximab phase is the standard institutional shape and integrates with the family's logistics.

When Braftovi is not the right call

Braftovi is the right answer for confirmed BRAF V600E or V600K-mutant disease in the three indications above. It is not the right answer for:

- BRAF wild-type disease (the biomarker gate is non-negotiable; BRAF wild-type melanoma, CRC, and NSCLC route to different targeted therapies, immune checkpoint inhibitors, or chemotherapy depending on biomarker profile and stage). - Severe hepatic impairment (Child-Pugh C); dose adjustment data is limited and the combination tolerability is unfavourable. - History of clinically significant uveitis; the BRAF plus MEK combinations carry an ophthalmologic risk that is unfavourable in this group. - Severe cardiac arrhythmia, congenital long QT syndrome, or significant baseline left ventricular dysfunction; the combination cardiac and QT signal is unfavourable. - Concurrent strong CYP3A4 inducers or inhibitors where dose adjustment cannot be achieved cleanly. - For the CRC indication only: RAS-mutant (KRAS or NRAS) disease, because cetuximab is not appropriate for RAS-mutant CRC. - Pregnancy. Effective contraception is required.

For confirmed BRAF V600-mutant melanoma where Braftovi plus Mektovi is not the chosen first-line, the alternatives in 2026 are dabrafenib plus trametinib (Tafinlar plus Mekinist), vemurafenib plus cobimetinib (Zelboraf plus Cotellic), and immune checkpoint inhibitor combinations (nivolumab plus ipilimumab; pembrolizumab; nivolumab plus relatlimab). Choice between the three BRAF plus MEK combinations is largely a tolerability decision in 2026. Choice between BRAF-targeted therapy and immunotherapy in BRAF V600-mutant melanoma is a real first-line decision and is not made by Reserve Meds. For confirmed BRAF V600E-mutant metastatic CRC, the alternatives are the original BEACON triplet (Braftovi plus Mektovi plus cetuximab) or standard chemotherapy regimens. For BRAF V600E-mutant NSCLC, dabrafenib plus trametinib is the older alternative.

Reserve Meds does not push a default. The page above describes the Braftovi pathway because Braftovi is the BRAF inhibitor the patient has asked about. If the conversation with the treating oncologist points toward dabrafenib plus trametinib or vemurafenib plus cobimetinib, the operational pathway shifts accordingly and we coordinate that pathway instead.

What Reserve Meds does on this case

We are a US-based concierge coordinator. We are not the prescriber and not the dispensing pharmacy. On a Saudi Braftovi case we build the document pack (pathology report, BRAF and RAS molecular diagnostic results, imaging, prior treatment history, oncologist clinical rationale letter for the combination), submit first-review requests to the chosen prescribing centre (KFSHRC, KAMC, KFMC, Princess Noorah Oncology, or a Dr Sulaiman Al Habib site), coordinate the insurance pre-authorisation conversation for both drugs in parallel where commercial insurance applies, support the NPP regulatory liaison for the NSCLC indication where the SFDA file lags the FDA timing, set up the first dispense of Braftovi at the chosen pharmacy and the first Mektovi dispense or first cetuximab infusion as appropriate, and stay with the case through the refill cycle for as long as the family wants concierge support. Clinical decisions remain with your treating medical oncologist and the multidisciplinary tumour board.

If you are not eligible for Braftovi because the biomarker is BRAF wild-type, or because RAS status excludes cetuximab in CRC, or for any other reason in the exclusion list above, reach out anyway. The alternatives in the BRAF wild-type and RAS-mutant spaces are real and well-described, and the same documentation pack and prescribing-centre relationships apply.

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

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