# Mekinist access in Bahrain

How Bahraini families pursue trametinib, the MEK1/2 inhibitor approved for BRAF V600-mutant melanoma and related indications, via the NHRA named-patient pathway.

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

## Quick orientation

Mekinist (trametinib) is an oral MEK1 and MEK2 kinase inhibitor approved by the US Food and Drug Administration in May 2013, originally as monotherapy for BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma. Subsequent FDA actions extended the label to combination use with dabrafenib (Tafinlar) for BRAF V600-mutant melanoma, BRAF V600E-mutant non-small cell lung cancer, BRAF V600E-mutant anaplastic thyroid cancer, and BRAF V600E-mutant solid tumors (tissue-agnostic) in adult and pediatric patients. The manufacturer is approximately Novartis. The dabrafenib plus trametinib combination has become a standard of care for BRAF V600-mutant melanoma, and the tissue-agnostic solid tumor approval has opened the door for use in rarer BRAF V600E-mutant cancers. For a Bahraini family weighing this option, the practical question is whether the molecule is registered locally, whether the registered version is in stock, and if not, how the NHRA named-patient pathway delivers it. Reserved for you.

## Why this drug is hard to source in Bahrain

The Kingdom of Bahrain is the smallest GCC market by population (approximately 1.7 million residents) and one of the most regulator-mature relative to its size. The National Health Regulatory Authority (NHRA) frequently approves novel oncology agents early in the region, but the volume of confirmed BRAF V600-mutant cases in Bahrain in any given quarter is small enough that hospital pharmacies do not always keep Mekinist on the shelf. The combination partner dabrafenib (Tafinlar) faces the same supply pattern; the two drugs are routinely co-dispensed when used in combination.

Bahraini patients with a BRAF V600-mutant malignancy therefore encounter one of three gaps. Some find that Mekinist is registered by the NHRA but their hospital pharmacy does not have it stocked at the moment they need to initiate. Some find that the combination partner is on the local register but Mekinist is not, requiring a parallel named-patient import for trametinib. Some find that neither molecule is registered locally, requiring a

paired named-patient import for both. The NHRA named-patient pathway exists to close the gap in each case.

The pace of oncology in BRAF V600-mutant disease is also part of why this case feels urgent. Melanoma and anaplastic thyroid cancer in particular progress quickly. Bahraini oncology services at Salmaniya Medical Complex, Bahrain Defence Force Hospital, and King Hamad University Hospital have the clinical capability to manage Mekinist therapy (including the combination dabrafenib partner and the dermatologic, cardiac, and ophthalmologic monitoring agenda), but the supply pathway frequently sits ahead of clinical readiness.

## The NHRA named-patient pathway

The pathway for a Bahraini-licensed oncologist to obtain a medicine that is not registered or not stocked locally is the unregistered-medicine import permit, administered through the NHRA's Pharmaceutical Product Regulation directorate. The framework allows hospitals and licensed pharmaceutical establishments to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority (typically the US FDA, EMA, MHRA, PMDA Japan, Health Canada, or the SFDA in Saudi Arabia) and a clinically suitable locally registered alternative is not available. Compassionate-use provisions cover serious or life-threatening illness where no alternative treatment is suitable.

A complete NHRA application for a Mekinist case typically includes the clinical justification letter from the treating oncologist (cancer diagnosis with histologic and molecular confirmation including the BRAF V600 mutation status from a validated assay, disease stage, prior systemic therapy history, performance status, and the case for the dabrafenib plus trametinib combination or trametinib monotherapy specifically), the treating physician's NHRA license verification, an anonymised patient identifier, full product details for Mekinist (brand name Mekinist, manufacturer approximately Novartis, strength 0.5 mg or 2 mg tablets, pack size, quantity requested, intended treatment duration), the destination dispensing facility name with NHRA pharmacy license number and pharmacy in charge, the chain-of-custody plan, and documentation of the FDA approval as the reference-authority anchor.

When the combination dabrafenib partner is also being imported under named-patient, a parallel NHRA application is typically filed at the same time. Co-filing avoids a clinical situation in which one half of the combination arrives while the other is delayed, which is operationally risky because the combination is dosed concurrently from the start of therapy.

Approval timelines for routine cases are 7 to 21 business days. Complex first-of-kind submissions extend to 4 to 6 weeks. Urgent oncology cases with documented progressive

disease can receive expedited review at the NHRA's discretion. The NHRA frequently compresses its review window when the SFDA, EDE, or another GCC authority has already registered the molecule, and Mekinist has registration footprints across multiple reference jurisdictions.

## Real costs in BHD and USD

The Bahraini dinar is pegged to the US dollar at approximately 1 BHD to 2.65 USD, and the peg has held since 1980. Mekinist's US wholesale acquisition cost for a typical 30-day supply at the 2 mg daily dose is approximately USD 13,000 to 15,000 per month, which translates to approximately BHD 4,900 to 5,700. The combination partner dabrafenib (Tafinlar) is approximately USD 12,000 to 13,000 per month at the standard 150 mg twice-daily dose. The combined monthly drug cost for the dabrafenib plus trametinib regimen is therefore approximately USD 25,000 to 28,000, or approximately BHD 9,400 to 10,600. Annual combined drug cost at maintenance dosing is approximately USD 300,000 to 336,000, or approximately BHD 113,000 to 127,000.

Mekinist tablets come in 0.5 mg and 2 mg strengths. Dose modifications for adverse events (cardiac dysfunction, retinal vein occlusion, interstitial lung disease, dermatologic reactions) can reduce the daily dose to 1.5 mg or 1 mg, which lowers monthly cost proportionally.

All-in delivered cost for a Bahraini patient pursuing Mekinist cross-border is the drug cost plus international logistics (approximately USD 400 to 1,500, or approximately BHD 150 to 565, per shipment), NHRA permit fees (nominal), customs handling at Bahrain International Airport, regulatory documentation handling, and the Reserve Meds concierge fee. Each fee line is itemised separately on the firm quote. When the combination partner dabrafenib is co-dispensed, the shipment can typically be consolidated to avoid duplicate logistics charges.

Insurance treatment of Mekinist in Bahrain varies by carrier. Sehati handles named-patient oncology case by case, with pre-authorisation the norm. Expatriate residents covered by employer or private insurance (Bahrain Kuwait Insurance / gig Bahrain, Solidarity Bahrain, Bahrain National Insurance, Medgulf, Bupa Arabia cross-border) each assess named-patient oncology individually. Reserve Meds supplies the documentation set that lets the insurer assess the case. We do not promise coverage from any insurer.

## Timing - what to expect

The NHRA permit itself is not the long pole. Routine NHRA submissions process in 7 to 21 business days; complex first-of-kind submissions extend to 4 to 6 weeks. The full Mekinist pathway from referral to first dose typically runs 3 to 8 weeks end to end. The BRAF V600 mutation confirmation sits at the front of the pathway and the result is required before the

prescription is written; molecular pathology at Bahraini reference laboratories or via Saudi reference centers typically returns in 7 to 14 business days. The first month's supply is then sourced, shipped, customs-cleared, and dispensed.

Combination therapy with dabrafenib is dosed concurrently from the start. Co-filing the two NHRA permits avoids the operational risk of one drug arriving without the other. Once the first cycle is dispensed, the renewal cycle establishes a steadier rhythm. Reserve Meds frames the case as an ongoing relationship with the treating oncologist and the dispensing pharmacy, with the first cycle as the slowest and subsequent cycles faster as the documentation foundation is already in place.

## What your physician needs

The clinical justification letter for a Mekinist NHRA submission carries the weight of the application. The treating oncologist's letter typically addresses the patient's cancer diagnosis with histology and molecular confirmation (the BRAF V600 mutation result from a validated assay, with specification of V600E, V600K, or other V600 variant where applicable), disease stage at presentation and at current decision point, prior systemic therapy history (immune checkpoint inhibitors where applicable, prior BRAF inhibitor monotherapy, prior targeted therapy or chemotherapy regimens, response and reason for change), current performance status, current organ function (ejection fraction baseline given the cardiac monitoring agenda, ophthalmologic baseline given the retinal vein occlusion class effect, pulmonary baseline given the interstitial lung disease risk), and the rationale for the dabrafenib plus trametinib combination or trametinib monotherapy now.

Three documents sit alongside the letter. The molecular pathology report confirming the BRAF V600 mutation is mandatory; trametinib without a documented BRAF V600 mutation is not on label except for a small set of post-prior-BRAF-inhibitor settings. The baseline echocardiogram or MUGA scan documenting ejection fraction is recommended given the cardiac dysfunction class effect. The ophthalmologic baseline is documented given the retinal vein occlusion and retinal pigment epithelial detachment class effects. The treating physician's NHRA license must be in active standing.

## Salmaniya Medical Complex and the Bahrain specialty-dispensing network

Bahrain's geography (a small island with short transit times between facilities) means the dispensing network is more compact than in larger GCC markets, and most named-patient oncology cases flow through a handful of tertiary centers. Salmaniya Medical Complex (SMC) in Manama is the kingdom's largest public tertiary hospital, operated by the Ministry of Health with approximately 1,200 beds and a full oncology and hematology service. SMC is

the default referral center for complex public-sector oncology and the single largest dispensing site in the country for specialty cancer medicines.

Bahrain Defence Force Hospital (BDF Royal Medical Services) in Riffa offers multispecialty tertiary services with a strong reputation for handling complex cases. The military supply chain and royal patronage give BDF operational latitude on advanced therapies that the public sector sometimes lacks. King Hamad University Hospital (KHUH) in Busaiteen is a 312-bed teaching hospital affiliated with the Royal College of Surgeons in Ireland - Medical University of Bahrain, with an active oncology and a growing cell-therapy program.

On the private side, Royal Bahrain Hospital and Bahrain Specialist Hospital in Manama, Al Hilal Hospital in Muharraq, and American Mission Hospital (the oldest private hospital in the Gulf, founded 1903) all hold specialty oncology practice and can host named-patient dispensing through their internal pharmacy infrastructure or through a Bahraini specialty importer. For physicians at smaller facilities without internal import infrastructure, the typical pattern is to route through a Bahraini specialty importer holding an NHRA pharmaceutical establishment license, or to refer the case into one of the tertiary centers above where the institutional pharmacy files on the prescribing physician's behalf.

For complex cases (rare BRAF V600E tissue-agnostic indications, pediatric anaplastic thyroid cancer, advanced melanoma with brain metastases), Bahraini oncologists sometimes coordinate with King Faisal Specialist Hospital and Research Centre in Riyadh via the King Fahd Causeway, where the SFDA registration is anchored and where case volume is higher.

## Pharmacovigilance and cold-chain

Mekinist is an oral medication and is shipped ambient. Cold-chain handling is not required for trametinib tablets, which simplifies the logistics relative to biologics. The combination partner dabrafenib is also ambient. The chain-of-custody documentation is still maintained from the US manufacturer through the importer to the dispensing pharmacy, and customs clearance at Bahrain International Airport flows through the NHRA permit framework.

Pharmacovigilance reporting obligations sit with the treating physician and the dispensing facility. Serious adverse drug reactions (those leading to hospitalisation, persistent disability, or a life-threatening condition) typically require NHRA reporting within 7 calendar days; other significant adverse events fall within 15 to 30 day windows. For Mekinist specifically, the monitoring agenda includes left ventricular ejection fraction (echocardiogram or MUGA at baseline and approximately every 2 to 3 months), ophthalmologic examination (baseline and as clinically indicated for the retinal vein occlusion and retinal pigment epithelial detachment class effects), pulmonary function (clinical and imaging surveillance for interstitial lung disease), dermatologic monitoring

(rash, hand-foot syndrome), and febrile reactions (the dabrafenib plus trametinib combination is associated with pyrexia that can require interruption and reduction).

## Common questions about Mekinist in Bahrain

**Will Sehati or my private insurance cover this?** Sehati and private insurers assess named-patient oncology case by case. Pre-authorisation is the norm. Reserve Meds supplies the documentation set that lets your insurer assess the case. We do not promise coverage from any insurer.

**Will my NHRA-licensed oncologist's letter be sufficient?** Yes. Any Bahraini-licensed medical oncologist or hematology-oncologist practicing in good standing has signing authority on the clinical justification letter. The NHRA license is national, not jurisdiction-specific within the kingdom, simplifying the documentation set relative to neighboring markets.

**Is Mekinist a controlled substance?** No. Mekinist is not a DEA scheduled substance. The federal narcotics framework does not apply. NHRA's standard pharmaceutical import documentation governs.

**Why Mekinist with dabrafenib and not Mekinist alone?** The dabrafenib plus trametinib combination has become a standard of care for BRAF V600-mutant melanoma and several other BRAF V600-mutant indications because the combination demonstrates better response rates, longer progression-free survival, and a more favorable safety profile (notably a lower incidence of cutaneous squamous-cell carcinoma) than BRAF inhibitor monotherapy. Trametinib monotherapy remains on label for specific clinical situations. The clinical choice rests with the treating oncologist. Reserve Meds does not steer the clinical decision.

**What about the tissue-agnostic BRAF V600E solid tumor indication?** The FDA's tissue-agnostic approval for the dabrafenib plus trametinib combination in unresectable or metastatic BRAF V600E-mutant solid tumors (in adult and pediatric patients with no satisfactory alternative treatment options) creates a pathway for rarer BRAF V600E-mutant cancers (low-grade glioma, biliary tract cancer, ovarian cancer with the mutation, and others). For these cases, the NHRA submission documentation typically references the tissue-agnostic indication directly and supplies the molecular pathology confirmation.

**Can I get Mekinist and Tafinlar together in one shipment?** Yes, when both are imported under named-patient. Co-filing the two NHRA permits and consolidating the shipment is the operational default. The two molecules are dispensed together at the dispensing pharmacy and dosed concurrently from the start of therapy.

## Where Reserve Meds fits in Mekinist cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating oncologist, the NHRA, the dispensing pharmacy, or the institutional clinical team. For a Mekinist case specifically, our work is identifying the FDA-approved product source for trametinib (and dabrafenib where combination therapy is planned), supplying the documentation set to your oncologist for the NHRA submission, coordinating the US-side release and shipment to the named Bahraini importer, and holding a single named coordinator through the case from first inquiry to dispense. We do not select the dispensing facility on the patient's behalf. We do not file pharmacovigilance reports on the physician's behalf. We do not promise insurance coverage from any carrier. Reserved for you.

## Next step

If a treating oncologist in Bahrain is weighing Mekinist for a family member with a BRAF V600-mutant malignancy, 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

- Mekinist clinical resource
- Tafinlar (dabrafenib) in Bahrain
- Mayzent in Bahrain
- Bahrain country page
- Melanoma condition page

## Sources


1. FDA approval, Mekinist (trametinib), Novartis, NDA approval May 2013 for BRAF V600-mutant unresectable or metastatic melanoma; subsequent indications including BRAF V600E NSCLC, anaplastic thyroid cancer, and tissue-agnostic BRAF V600E solid tumors.
2. Bahrain National Health Regulatory Authority (NHRA), Pharmaceutical Product Regulation directorate, unregistered-medicine import permit framework.
3. Central Bank of Bahrain, USD-BHD peg at 1 BHD = 2.65 USD (established 1980).

**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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