Tafinlar access in Jordan: the JFDA named-patient pathway

How Jordanian oncology and hematology teams pursue dabrafenib, a selective BRAF kinase inhibitor, for BRAF V600 mutation-positive melanoma, non-small cell lung cancer, anaplastic thyroid cancer, and pediatric low-grade glioma.

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

Quick orientation

Tafinlar (dabrafenib) is an oral, selective BRAF kinase inhibitor manufactured by Novartis. The drug was first approved by the US Food and Drug Administration in May 2013 for BRAF V600E mutation-positive unresectable or metastatic melanoma. The indication set has expanded substantially over the past decade and now includes BRAF V600E or V600K mutation-positive melanoma, BRAF V600E mutation-positive metastatic non-small cell lung cancer in combination with trametinib (Mekinist), locally advanced or metastatic BRAF V600E anaplastic thyroid cancer with no satisfactory locoregional treatment options in combination with trametinib, and pediatric low-grade glioma with a BRAF V600E mutation in patients aged 1 year or older requiring systemic therapy. The drug is dispensed as 50 mg and 75 mg capsules. The standard adult monotherapy dose is 150 mg orally twice daily; combination therapy dosing is the same when paired with trametinib 2 mg orally once daily. Reserved for you.

Why this drug is hard to source in Jordan

Tafinlar is well known in Jordanian oncology practice. King Hussein Cancer Center, Jordan University Hospital, King Abdullah University Hospital, and the larger private specialty hospitals all treat patients with BRAF mutation-positive melanoma, NSCLC, and thyroid cancer. Whether Tafinlar is currently held in stock at a specific hospital pharmacy on the day a patient needs it, however, is a different question. The drug is registered in Jordan, but stocking depth varies by institution and by the timing of the institution's procurement cycle.

Three patterns drive the JFDA named-patient pathway for a Tafinlar case in Jordan. First, registered but not stocked. The drug is on the JFDA register, but the dispensing institution

does not have it in pharmacy at the time the oncologist prescribes it, and the local distributor lead time does not match the patient's clinical window. Second, pediatric low-grade glioma indication. The pediatric LGG indication was added to the US label in March 2023 and the supporting combination is dabrafenib plus trametinib oral suspension or capsules; the pediatric oral suspension formulation may not be stocked in country even where the adult capsule is. Third, the combination with trametinib (Mekinist) requires both molecules together; when one of the two is short, the regimen falls apart, and the named-patient permit on the constrained component restores the regimen.

The treating oncologist documents the clinical justification, the JFDA Drug Directorate reviews, and the medicine is imported in the patient's name for dispensing at a JFDA-licensed facility in Jordan.

The JFDA named-patient pathway

The Jordan Food and Drug Administration, headquartered in Amman, administers the personal-use and named-patient import permit under the Drug Directorate. The pathway allows hospitals, licensed pharmaceutical importers, and retail pharmacies operating under physician prescription to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority (US FDA, EMA, MHRA, Health Canada, TGA, PMDA) and a clinically equivalent locally registered alternative is not suitable or is not available.

For a Tafinlar case, the standard application set applies, with three additions specific to BRAF-targeted therapy. First, the clinical justification letter documents the BRAF V600 mutation result, with the pathology report or molecular pathology report referenced or attached. Mutation testing is typically done on tumor tissue by immunohistochemistry, polymerase chain reaction, or next-generation sequencing, and the result is the entry criterion for the entire targeted-therapy class. Second, where the patient is on the combination regimen with trametinib (Mekinist), the application typically captures both molecules in a coordinated import or in two parallel applications so the dispensing aligns. Third, for pediatric cases, the patient age, weight, body surface area, and the dose calculation are documented; pediatric LGG dosing is weight-based and the dispensing institution typically captures the calculation on the dispensing record.

A complete JFDA application for a Tafinlar case typically includes the clinical justification letter from the treating oncologist, the oncologist's JPA membership and MOH registration verification, the patient identifier (national civil status registry number for Jordanian nationals, passport copy for non-nationals), full product details (brand name Tafinlar, generic name dabrafenib, manufacturer Novartis, 50 mg or 75 mg capsules, pack size, quantity, intended treatment duration), the destination dispensing facility name and JFDA pharmaceutical establishment license number, the BRAF V600 mutation documentation,

and a chain-of-custody plan. Tafinlar capsules are stored at room temperature (20 to 25 degrees Celsius) with limited excursions, so cold-chain is not required. Approval timelines run 7 to 21 calendar days from a complete submission.

Real costs in JOD and USD

The US wholesale acquisition cost for Tafinlar is approximately USD 12,000 to 13,000 per 30-day supply at the standard adult dose of 150 mg twice daily (120 capsules of 75 mg per month). In JOD at the 0.71 peg, this is approximately JOD 8,500 to 9,250 per month. Annual cost at the adult monotherapy dose is approximately USD 144,000 to 156,000 (approximately JOD 102,000 to 111,000).

For the combination regimen with trametinib (Mekinist), the combined drug cost roughly doubles, with Mekinist adding approximately USD 11,000 to 12,000 per 30-day supply at the standard 2 mg once-daily dose. The combination annual cost is approximately USD 280,000 to 320,000 (approximately JOD 199,000 to 227,000). Pediatric LGG dosing is weight-based and the dispensed quantity scales with the patient body surface area.

International logistics for a room-temperature oral oncology agent into Jordan typically runs USD 400 to 800 (approximately JOD 285 to 570). JFDA permit fees and Jordan Customs handling are nominal relative to the drug cost. Regulatory documentation handling and the Reserve Meds concierge fee are itemised separately on every firm quote.

On the insurance side, RMS and MOH schemes cover targeted oncology therapy for their beneficiaries when the case is properly documented and the dispensing occurs at an RMS or MOH facility. KHCC, as the national oncology reference center operated by the King Hussein Cancer Foundation, has internal mechanisms that handle high-cost oncology therapy for Jordanian patients through a combination of insurance, charitable support, and patient contribution. Private insurers assess named-patient oncology cases individually and most require pre-authorisation. Reserve Meds supplies the documentation set that lets your insurer assess the case. We do not promise coverage from any insurer.

Timing, what to expect

The JFDA permit itself processes in approximately 7 to 21 calendar days from a complete submission. The full timeline from the first physician contact to the patient receiving the first dose is typically 3 to 6 weeks for a Tafinlar case, broken down approximately as follows. Initial documentation kit delivery to the physician runs 24 to 48 hours from waitlist confirmation. The treating oncologist clinical justification letter and BRAF mutation result assembly typically takes a few days to one week if the mutation testing is already complete; if the mutation status is pending, the timeline lengthens to allow testing to return. The JFDA application filing and approval window runs 7 to 21 calendar days. US-side sourcing and

shipment scheduling, run in parallel with the JFDA review, takes 3 to 7 business days. Customs clearance at Queen Alia International Airport and delivery to the dispensing pharmacy typically takes 1 to 3 business days post-shipment.

The dose schedule is 150 mg orally twice daily on an empty stomach (at least 1 hour before or 2 hours after a meal), at intervals of approximately 12 hours. For BRAF V600E NSCLC, anaplastic thyroid cancer, and adjuvant melanoma, the combination with trametinib 2 mg once daily applies. Most patients see initial response on imaging within 6 to 8 weeks for advanced melanoma. Treatment continues until disease progression or unacceptable toxicity.

What your physician needs

The clinical justification letter for a Tafinlar JFDA submission is the cornerstone of the application. The treating oncologist letter typically addresses the patient diagnosis (cancer type, stage, BRAF V600 mutation status with the pathology report referenced), the prior systemic therapy history including any prior immunotherapy (anti-PD-1, anti-CTLA-4) where applicable, the rationale for BRAF-targeted therapy now, the planned regimen (monotherapy versus combination with trametinib), the dose and duration, and the monitoring plan for the known class toxicities (pyrexia, cutaneous squamous cell carcinoma, secondary cutaneous malignancies, uveitis, hyperglycaemia, hepatic effects).

The treating oncologist JPA membership and MOH registration must be in active standing. The destination dispensing facility (the hospital pharmacy or specialty pharmacy named in the application) must hold a JFDA pharmaceutical establishment license. The BRAF V600 mutation result must be documented from a recognised molecular pathology laboratory. The patient identifier is included on the application. For pediatric cases, the weight-based dose calculation and the parent or legal guardian consent are part of the dispensing record.

King Hussein Cancer Center and the Jordan specialty-dispensing network

For oncology cases, King Hussein Cancer Center in Amman is the natural Jordanian dispensing institution. KHCC holds Joint Commission International disease-specific cancer accreditation, operates a comprehensive in-house import pharmacy, routinely files JFDA named-patient permits, and handles a high volume of BRAF mutation-positive cancer cases through its melanoma, lung, and thyroid programmes. KHCC also handles pediatric oncology, including pediatric low-grade glioma cases, through its pediatric oncology service.

Outside KHCC, the academic teaching hospitals (Jordan University Hospital in Amman, King Abdullah University Hospital in Irbid) operate oncology service lines, hold JFDA

pharmaceutical establishment licenses, and can serve as the dispensing facility for adult oncology cases. On the private side, Istishari Hospital, Specialty Hospital, and Arab Medical Center each have oncology service lines and either operate an in-house import pharmacy or route through an Amman-based specialty pharmaceutical importer. For regional patients (Iraq, Palestine, Syria, Yemen, Libya, Sudan) who have travelled to Jordan for oncology care, KHCC is the most common dispensing institution because of its regional referral pattern and its experience handling the named-patient pathway for non-Jordanian patients.

For oncologists at smaller hospitals or private clinics without internal import infrastructure, the standard pattern is to route through an Amman-based specialty pharmaceutical importer that holds the JFDA establishment license, files the permit on the prescribing physician behalf, performs customs clearance at Queen Alia International Airport, and delivers the medicine to the prescribing physician pharmacy under chain-of-custody documentation.

Pharmacovigilance and cold-chain

Tafinlar capsules are stored at room temperature (20 to 25 degrees Celsius) with permitted excursions to 15 to 30 degrees Celsius. Cold-chain transport is not required. The shipping packet captures temperature trace from US release through Jordanian dispensing for quality assurance purposes, but the operational sensitivity is much lower than for a refrigerated biologic.

Jordan operates a national pharmacovigilance system administered by the JFDA Drug Directorate, and is a member of the WHO Programme for International Drug Monitoring through the Uppsala Monitoring Centre. The treating oncologist and the dispensing facility share the duty to report adverse drug reactions through the JFDA portal at jfda.jo. The Tafinlar safety profile is well-characterised; common adverse events include pyrexia (manageable with dose interruption and corticosteroids), cutaneous squamous cell carcinoma and other secondary cutaneous malignancies (requires baseline and periodic dermatology evaluation), uveitis (requires baseline and periodic ophthalmology evaluation in symptomatic patients), hyperglycaemia, and hepatic effects. Serious adverse reactions are reported within 15 calendar days; other significant adverse events fall within 30-day or 90-day windows depending on severity.

Common questions about Tafinlar in Jordan

Will RMS, MOH civil-servant scheme, or private insurers cover this? RMS and MOH schemes typically cover targeted oncology therapy for their beneficiaries when the case is properly documented and the dispensing occurs at an RMS or MOH facility. KHCC has internal mechanisms for high-cost oncology therapy. Private insurers (MetLife, Generali,

Arab Orient, Jordan Insurance, Mediterranean and Gulf) assess named-patient oncology cases individually. We supply the documentation set that lets your insurer assess the case.

Is BRAF mutation testing available in Jordan? Yes. KHCC operates an in-house molecular pathology laboratory and is the regional reference for BRAF, EGFR, ALK, and other actionable mutation testing. JUH and KAUH also offer molecular pathology testing. For smaller institutions, samples are typically sent to KHCC or to a Jordanian commercial reference laboratory.

Can my regional patient (Iraq, Palestine, Syria) receive Tafinlar through Jordan? Yes, where the patient is admitted at a Jordanian institution and the dispensing occurs at a JFDA-licensed facility in Jordan. The named-patient permit is filed in the patient name with their country-of-residence passport as the identifier, and the dispensing is at the Jordanian institution. Continuation therapy after the patient returns home routes through the patient home-country regulatory pathway, not through the Jordanian permit.

What about the combination with trametinib (Mekinist)? For combination indications (BRAF V600E NSCLC, anaplastic thyroid cancer, adjuvant melanoma), the regimen is dabrafenib plus trametinib. Both molecules are coordinated together. The JFDA permit captures both molecules in a coordinated application or in two parallel applications so dispensing aligns. Mekinist requires refrigerated storage (2 to 8 degrees Celsius) so the logistics for Mekinist differ from those for Tafinlar.

Is Tafinlar a controlled substance? No. Tafinlar is not a DEA scheduled substance. The Anti-Narcotics Department coordination does not apply.

Where Reserve Meds fits in Tafinlar cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating oncologist, the JFDA, the dispensing pharmacy, or the receiving institution. For a Tafinlar case, our work is treating-physician coordination on the documentation kit, US-side sourcing of the manufacturer or authorised distributor product, ambient shipment to the Jordanian importer or hospital pharmacy of record, and a single named coordinator through the case. Where the case is a combination regimen with Mekinist, we coordinate both molecules together so the dispensing aligns. The clinical decisions, the JFDA filing, and the dispensing all sit with your Jordanian oncologist and the dispensing facility. Reserved for you.

Next step

If a treating oncologist in Jordan is weighing Tafinlar for a patient with BRAF V600 mutation-positive cancer, 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

- Tafinlar clinical resource
- Tafinlar in Saudi Arabia
- Tafinlar in the UAE
- Mekinist in Jordan
- Jordan country page
- Melanoma condition page

Sources

1. FDA approval, Tafinlar (dabrafenib), Novartis (originally GlaxoSmithKline), NDA approval May 2013 for BRAF V600E mutation-positive unresectable or metastatic melanoma; subsequent indication expansions through 2023.
2. Jordan Food and Drug Administration, jfda.jo, Drug Directorate framework for personal-use and named-patient import permits; Law No. 41 of 2008.
3. Central Bank of Jordan, fixed exchange rate framework, JOD-USD peg at approximately 0.71 JOD per USD since 1995.
4. King Hussein Cancer Center, khcc.jo, institutional profile, Joint Commission International disease-specific cancer accreditation, regional referral pattern.

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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