

## Tafinlar

Saudi Arabia · access guide

# How to access Tafinlar from Saudi Arabia, the named-patient import pathway, 2026

By Reserve Meds · Clinical & regulatory team · Last reviewed 2026-04-23

A Saudi Arabiaian patient diagnosed with BRAF V600E or V600K mutant advanced melanoma may receive a prescription for Tafinlar (dabrafenib) from their treating medical oncologist, typically in combination with Mekinist (trametinib). Tafinlar is FDA-approved in the United States across several BRAF-mutant cancers including melanoma, NSCLC, anaplastic thyroid cancer, and specific paediatric indications. In Saudi Arabia, Tafinlar may not be routinely stocked in all tertiary oncology pharmacies, which is why your oncologist may be coordinating a named-patient import pathway on your behalf.

This guide explains the legal pathway, what documentation your physician needs, typical timing and cost bands, and where Reserve Meds fits in.

## The clinical situation

Tafinlar is an oral selective BRAF kinase inhibitor. Eligibility requires molecular confirmation of a BRAF V600 mutation. The manufacturer is Novartis. Dosing in melanoma is typically 150 mg orally twice daily in combination with trametinib. Monitoring includes pyrexia (a distinctive Tafinlar-family effect), skin surveillance for cutaneous malignancies, QTc, glucose, and liver enzymes. Your oncologist will confirm BRAF status and combination planning.

## Is Tafinlar legally importable into Saudi Arabia?

Yes, through the Saudi Food and Drug Authority (SFDA) named-patient import framework, administered via the administering hospital's importing pharmacy and the SFDA Drug Directorate. The Saudi Arabia has a mature named-patient mechanism that supports cross-border access to specialised oncology products.

The framework rests on four anchors: (a) the medicine is approved by a recognised reference authority (FDA qualifies), (b) no clinically equivalent locally registered alternative is suitable for the patient, (c) the treating physician takes clinical responsibility for use, and (d) the importing party documents chain of custody from the US source to the administering facility. Applications are typically filed by the tertiary centre's importing pharmacy on the physician's behalf.

## How the pathway works, step by step

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1. **Consultation with your treating oncologist.** The decision to prescribe Tafinlar in combination with Mekinist is clinical, based on BRAF status and tumour type. Your oncologist documents the rationale.
2. **Administering facility identification.** A Saudi Arabiaian tertiary oncology centre with an importing pharmacy files on behalf of the physician.
3. **SFDA named-patient application.** Your physician or the hospital's importing pharmacy files an application with SFDA including clinical rationale, combination regimen, patient identifier, product details, and chain-of-custody plan.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure product from the manufacturer's authorised distribution chain under DSCSA.
5. **Temperature-controlled shipment.** Tafinlar is a stable oral capsule; shipments travel with tamper-evident packaging and end-to-end documentation.
6. **Arrival and dispensing support.** Your oncologist remains the treating clinician. Reserve Meds coordinates re-supply ahead of cycle end to avoid treatment gaps.

## What documentation your physician needs

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Your physician will typically need to provide:

- A clinical rationale letter confirming BRAF status, tumour type, combination regimen, prior therapies, and Tafinlar as the indicated treatment
- Verification of their Saudi Arabiaian medical licence (JMC / MOH)
- A current prescription naming the product, strength, and quantity
- Patient identifier (anonymised reference preferred)
- The planned treatment cadence (continuous twice-daily therapy with monthly re-supply)

Reserve Meds provides a physician documentation kit bundling the templates SFDA reviewers expect to see for oncology oral therapies under named-patient import.

## Costs and timing

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Tafinlar's US cash-pay drug-only reference price for a 30-day supply sits in an indicative 2026 drug-only range (delivered quote issued at intake) of roughly USD 12,000-14,000. The combination partner (Mekinist) is costed separately. Logistics, SFDA documentation handling, and concierge coordination add incremental cost; Reserve Meds issues a full transparent quote at the start of intake.

Indicative timing for first shipment arrival after cohort intake opens is 7-14 days from the moment a complete SFDA application is submitted. Subsequent re-supply cycles are generally faster once the pathway is established.

*Fulfillment availability is limited to our first cohort, and all timelines published on this site are indicative. If your clinical situation is time-sensitive, tell us at intake. We triage accordingly.*

## Reserve Meds's role

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Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Tafinlar specifically, we provide:

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody.
- **Documentation.** Regulatory documentation package for your physician and for SFDA review, covering the full combination regimen.
- **Logistics.** Temperature-stable shipment and chain-of-custody coordination.
- **Concierge case lead.** A named point of contact for your family and your physician throughout the process.

**What we do not do:** we are not the prescriber, we do not practise medicine, and we are not the dispensing pharmacy. All clinical decisions remain with your treating oncologist.

## Frequently asked

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**Is this legal in Saudi Arabia?** Yes, when executed through the SFDA named-patient framework with appropriate documentation. The pathway has been used routinely across oncology for many years. See our trust and compliance page.

**Does Tafinlar cause fevers?** Pyrexia is a well-described effect of Tafinlar plus trametinib. Your oncologist will outline management (dose modification, antipyretics). We coordinate supply, not clinical management.

**What if my oncologist has not done this before?** Named-patient import is an institutional process your oncologist's hospital will have encountered. Our documentation kit closes the gap for first-time applicants.

**Will private insurance cover this?** Cash-pay is the default. Some Saudi Arabiaian private insurers reimburse named-patient imports on case-by-case approval; we supply documentation for your submission but do not process insurance claims directly.

### *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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### Reserve Meds

*reserved for you.*

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.

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