Rozlytrek

Oman · access guide

How to access Rozlytrek from Oman, the named-patient import pathway, 2026

By Reserve Meds, Clinical and regulatory team. Last reviewed 2026-05-13.

An Omann patient with a solid tumor harbouring an NTRK gene fusion without a known acquired resistance mutation (across adult and pediatric populations age one month and older), where the tumor is metastatic or surgical resection is likely to result in severe morbidity and there is no satisfactory alternative therapy, or with ROS1-positive metastatic non-small cell lung cancer, may receive a prescription for Rozlytrek (entrectinib) from their treating oncologist. Rozlytrek is FDA-approved in the United States and manufactured by Genentech, a member of the Roche Group. It is a tyrosine kinase inhibitor administered orally with central nervous system penetration. Local availability of Rozlytrek in Oman can be inconsistent: the drug may not be on every tertiary cancer center's standing formulary, the specific indication may not match what is locally registered, or the strength required may be back-ordered. When that happens, a named-patient import pathway through DGPADC remains a legitimate route for the patient whose physician has already prescribed the drug.

This guide explains the pathway, the documentation your physician needs, typical costs and indicative timing, and where Reserve Meds fits in.

The clinical situation

Rozlytrek is a small-molecule tyrosine kinase inhibitor of TRKA, TRKB, TRKC, ROS1, and ALK with CNS penetration. Standard adult dosing is 600 mg orally once daily. Pediatric dosing is body-surface-area based. Confirmation of an NTRK1, NTRK2, or NTRK3 gene fusion (for tumor-agnostic indication) or a ROS1 fusion (for NSCLC) by an FDA-approved companion diagnostic, or an equivalent locally accredited NGS test, is required before initiation. Baseline workup per FDA labeling includes complete blood count, hepatic function, renal function, uric acid, ECG (QTc prolongation is a known signal), echocardiogram for LVEF in patients with cardiac risk factors, ophthalmologic and neurologic baseline, and pregnancy testing where applicable. Important warnings include congestive heart failure, CNS effects (cognitive impairment, mood disorders, dizziness, sleep disturbance), skeletal fractures, hepatotoxicity, hyperuricemia, QTc prolongation, vision disorders, and embryo-fetal toxicity. Your oncologist will discuss the risk-benefit profile and schedule monitoring before initiating therapy.

Is Rozlytrek legally importable into Oman?

Yes, through the Directorate General of Pharmaceutical Affairs and Drug Control (DGPADC) named-patient and personal-use import framework, coordinated with the treating hospital pharmacy. The Oman has an established pathway for specialty oncology medicines approved by reference authorities (US FDA, EMA, MHRA) but not registered locally for the specific indication, or not consistently stocked.

The DGPADC named-patient route allows an Oman-licensed physician to request import of a medicine when: (a) the medicine is approved by a recognised reference authority, (b) no clinically equivalent locally registered alternative is suitable for the patient's indication and history, (c) the treating physician takes clinical responsibility for use, and (d) chain of custody is documented from the US source to the administering facility.

How the pathway works, step by step

1. **Consultation with your treating oncologist.** The prescribing decision is clinical. Your oncologist documents the indication, NTRK or ROS1 fusion status (with NGS report), prior therapies, and rationale for Rozlytrek.
2. **Baseline screening.** CBC, LFTs, renal function, uric acid, ECG, neurologic and ophthalmologic baseline, and pregnancy testing where applicable are confirmed and documented.
3. **DGPADC named-patient application.** Your oncologist or the hospital's import pharmacy files the application with clinical rationale, fusion status documentation, patient reference, product strength (100 mg or 200 mg capsules), quantity requested, and chain-of-custody plan.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure product from Genentech's authorised distribution under DSCSA chain-of-custody.
5. **Shipment.** Rozlytrek is an oral capsule with controlled-room-temperature storage requirements. Shipments include temperature-monitored packaging and tamper-evident seals.
6. **Arrival and first dose.** The dispensing pharmacy releases product against the physician's prescription, and your oncologist initiates therapy with scheduled ECG, lab, and neurologic follow-up.

What documentation your physician needs

Your physician will typically need to provide:

- A clinical rationale letter confirming diagnosis, NTRK or ROS1 fusion status (with NGS or companion diagnostic report), prior therapy history, and Rozlytrek as the indicated next step
- Verification of their Oman medical licence (MCI or state medical council registration)
- A patient identifier, anonymised reference where privacy is preferred
- Documented pre-treatment screening (CBC, LFTs, renal, uric acid, ECG, neurologic exam) consistent with FDA labeling
- The planned dosing strength and schedule (600 mg once daily for adults; BSA-based for pediatric)
- A discussion note on the QTc, CHF, CNS, and ophthalmologic monitoring plan

Reserve Meds provides a physician documentation kit that bundles the templates DGPADC reviewers expect to see for TRK and ROS1 targeted therapy.

Typical costs and indicative timing

Reserve Meds gives you a drug-only reference range plus a transparent delivered quote at intake. As an illustrative composite case, the US cash-pay reference range for a 30-day supply of Rozlytrek (600 mg daily) sits in an indicative 2026 band of roughly USD 19,000 to 23,500. International logistics, DGPADC documentation handling, shipping, and concierge coordination add incremental cost. The delivered quote we issue at intake shows each line separately.

Indicative timing for first dose after cohort intake opens is approximately 3 to 6 weeks from the moment a complete application is submitted to DGPADC, assuming the documentation package and NTRK/ROS1 fusion report are clean on first pass. Refills ship on a rolling cadence aligned to your monthly supply.

Service availability is limited to our first cohort. All timelines are indicative, not guarantees.

Where Reserve Meds fits in

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

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody from manufacturer to export.
- **Documentation.** Regulatory package tailored for your physician and for DGPADC review, including TRK and ROS1 inhibitor monitoring templates.
- **Logistics.** Temperature-monitored, internationally tracked shipment to your named dispensing facility.
- **Concierge case lead.** A named point of contact for your family and your physician across the full case arc.

We are a coordinator. We are not the prescriber, not a pharmacy, and not a dispensing facility. All clinical decisions remain with your treating oncologist, and dispensing sits with the licensed Omann pharmacy of record. Reserve Meds operates on cash-pay only and does not bill insurance.

Frequently asked

Is this legal in Oman? Yes, when executed through the DGPADC named-patient and personal-use framework with appropriate documentation, clinical rationale, and a licensed dispensing facility. The pathway is routinely used across Omann oncology.

How does Rozlytrek compare with Vitrakvi (larotrectinib)? Both are FDA-approved for NTRK fusion-positive solid tumors. Rozlytrek also covers ROS1-positive NSCLC and has documented CNS penetration. Vitrakvi is a more selective TRK inhibitor. Your oncologist makes that determination based on your tumor type, CNS disease status, and side-effect profile considerations.

What about the cardiac warning? Congestive heart failure is a known signal with Rozlytrek. Your oncologist will perform baseline cardiac assessment in patients with cardiac risk factors and monitor symptoms per labeling. Reserve Meds does not make that clinical judgement, your physician does.

Will my private health insurance cover this? Cash-pay is the default posture. Some Omann private insurers reimburse named-patient oncology imports on a case-by-case basis when the documentation package is strong. We supply documentation for your submission but do not process insurance claims.

What if my oncologist has not filed a named-patient request before? Named-patient import is an institutional process most major Omann cancer centers (Tata Memorial, AIIMS, Apollo, Fortis, HCG, Max) have encountered. Our documentation kit is written for first-time applicants and tracks what DGPADC reviewers commonly ask for.

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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