Rhapsido

Turkey · access guide

Rhapsido access in Turkey: the TITCK named-patient pathway

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.

Quick orientation

Patients in Turkey access Rhapsido (remibrutinib) for chronic spontaneous urticaria (CSU) in adults inadequately controlled by H1 antihistamines through the TITCK named-patient pathway, a the Turkish Medicines and Medical Devices Agency (Turkiye Ilac ve Tibbi Cihaz Kurumu)-administered mechanism that allows a Turkish-licensed physician at a registered facility to import the FDA-labelled product for a specific named patient. This page details the documentation, approval timeline, and real cost in TRY.

Why Turkish patients need Rhapsido through the named-patient pathway

The Republic of Turkiye operates a structured pharmaceutical regulatory environment. Rhapsido (remibrutinib) is regulated through TITCK (the Turkish Medicines and Medical Devices Agency (Turkiye Ilac ve Tibbi Cihaz Kurumu)) channels, and a Turkish family asking for Rhapsido is rarely asking for a medicine that does not exist locally. They are usually asking for a precise version of it that the local market has not caught up to.

Four converging patterns drive these cases. First, indication lag. Rhapsido's newer FDA-approved indications and dosing expansions often reach local registration 12 to 36 months after the US label. A family whose treating physician has documented a clear FDA-label fit may still find that the local label has not caught up. Second, presentation gaps. The exact strength, weight-banded dose, or pen format the prescriber needs may not be stocked at the local agent even when the medicine is registered. Third, payer denial. SGK public coverage with Allianz Sigorta, Anadolu Sigorta, and Acibadem Sigorta employer plans each assess specialty therapies case by case, and step-therapy or formulary rules often produce denials even when the drug is on the local register. Cash-pay families pursue cross-border supply rather than wait through appeals. Fourth, continuity of supply. When a US-stable patient relocates to Turkey or visits family for an extended period, maintaining the original FDA-sourced regimen matters more than switching to a different local presentation.

In each pattern, the TITCK named-patient pathway is the mechanism that connects a Turkish-licensed physician's clinical decision with US-sourced, FDA-labeled product for a specific patient. Clinically, Rhapsido is an oral covalent Bruton's tyrosine kinase (BTK) inhibitor that blocks mast-cell and B-cell activation, and the named-patient route preserves that mechanism rather than substituting a non-equivalent local option.

The TITCK named-patient pathway for Rhapsido

The pathway for a Turkish-licensed physician to obtain a medicine that is not registered or not stocked locally is the named-patient supply pathway administered by TITCK (Turkiye Ilac ve Tibbi Cihaz Kurumu) under the Turkish Ministry of Health, which allows a treating physician at a registered facility to apply for the import of an unregistered medicine for a specific named patient where the medicine is approved by a recognised reference authority and no clinically equivalent locally registered option is suitable; in practice the import is routed through the Turkish Pharmacists Association (TEB) supply channel for foreign medicines. The framework allows registered healthcare facilities 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, or Health Canada) and a clinically equivalent locally registered alternative is not suitable. For Rhapsido specifically, the clinical justification typically frames the case around the precise FDA-approved indication and the documented gap in the local route.

A complete application includes a clinical justification letter from the treating physician (diagnosis, severity, prior therapies, why this specific drug, why the locally stocked option is not suitable for this case), the treating physician's Turkish medical license verification through the Turkish Medical Association (TTB) and the Ministry of Health licensing directorate, an anonymised patient identifier where the TITCK submission allows, full product details (brand name, generic name, manufacturer, strength, dosage form, pack size, quantity requested, intended treatment duration), the destination dispensing facility name, license number, and pharmacy in charge, and a chain-of-custody plan describing how the medicine will move from the US manufacturer through the importer to the dispensing pharmacy.

For Rhapsido, the clinical justification angle typically rests on one or more of three documented elements: a pediatric or weight-banded request that fits the FDA label but not the local label, a denied biologic or specialty claim where prior step-therapy has been documented, or a continuity-of-supply request for a patient previously stabilised on the US-sourced presentation. The treating physician documents the relevant clinical criteria for the prescribed indication: severity scores, biomarker levels, prior therapy failures, and the rationale for Rhapsido versus the next-in-line local alternative.

Approval timelines for routine cases are typically 10 to 25 business days. Complex cases (rare indication, larger quantities, first import of a given pediatric or weight-banded format) can extend to 6 to 10 weeks. TITCK retains discretion on timing, and we do not promise specific durations.

Where Rhapsido gets dispensed in Turkey

A small group of Turkish institutions handle named-patient imports as established workflow, with in-house import pharmacy infrastructure and physicians experienced with the application set. Because chronic spontaneous urticaria is managed by dermatology and allergy specialties, the appropriate tertiary centres are dermatology and allergy / immunology services. Centres that meet this profile include Hacettepe University Hospital Dermatology in Ankara, Istanbul University Cerrahpasa Dermatology in Istanbul, and Acibadem Healthcare Group Dermatology in Istanbul. Rhapsido is an oral 25 mg tablet taken twice daily and is stored at ambient room temperature; the dispensing pharmacy's standard solid-dose handling and chain-of-custody log are sufficient.

For physicians at smaller hospitals without internal import infrastructure, the common pattern is to route through a specialty importer that holds a pharmaceutical establishment license and files the TITCK application on the prescribing physician's behalf. The medicine then moves into the prescribing hospital's outpatient or specialty pharmacy under chain-of-custody documentation.

Real cost picture for Rhapsido in Turkey

The published US WAC for Rhapsido is USD 4,521 per 30-day supply, set by Novartis at the September 2025 launch, which is approximately USD 54,252 per year. At an indicative rate of 39.0 TRY per 1 USD (live FX confirmed at intake), that converts to approximately TRY 176,319 per 30-day supply and TRY 2,115,828 per year. These are reference anchors; the final quote is confirmed at intake on live FX and verified sourcing channel. See /trust for sourcing methodology.

International logistics for shipment to Turkey typically runs USD 400 to USD 1300 depending on destination city, urgency, and presentation (cold-chain biologics carry the higher end of the range; ambient oral solids the lower). The Republic of Turkiye customs and TITCK permit fees are nominal relative to drug cost. Reserve Meds' concierge fee is itemised separately on every firm quote.

On the insurance side, SGK public coverage with Allianz Sigorta, Anadolu Sigorta, and Acibadem Sigorta employer plans each assess named-patient imports case by case. Some reimburse fully when the medicine is on their formulary even if not stocked, some reimburse a percentage subject to copay, and many require pre-authorisation. We do not promise coverage from any insurer. US manufacturer copay cards and patient assistance programs do not extend internationally; cross-border patients pay cash or rely on local payer coverage.

Typical timeline for Rhapsido in Turkey

TITCK routine processing is typically 10 to 25 business days from a complete filing. International logistics adds 2 to 5 additional days depending on whether the presentation is ambient or cold-chain, the dispensing city, and customs clearance. End-to-end, most routine adult cases complete within 3 to 6 weeks from first complete documentation. Pediatric, weight-banded, or first-import cases can run slightly longer because presentation selection and first-import scrutiny can extend TITCK review.

For temperature-sensitive products, the dispensing facility must maintain validated storage with continuous monitoring; the manufacturer's room-temperature excursion runway on the FDA label informs how we plan the Gulf, South Asia, or North Africa shipping lane, and the cold chain is broken only at the dispensing pharmacy under documented control.

When a case is on a clinical clock (a flare, a new diagnosis with an active disease, or a treatment cycle scheduled at the dispensing centre), the practical question is which step controls the timeline. In our experience the binding step is rarely the TITCK review itself when the application is filed clean; it is usually documentation completeness on the prescriber's side or, for cold-chain biologics, the dispensing facility's storage and monitoring confirmation. The intake is where we lock the case-team contact, gather the documents in parallel, and start the US sourcing clock so that approval and product land in the same week rather than serially.

What your physician needs to provide

For a Turkish-licensed specialist prescribing Rhapsido through the TITCK pathway, the clinical justification letter is the cornerstone of the application. The letter typically documents the patient's confirmed diagnosis for chronic spontaneous urticaria (CSU) in adults inadequately controlled by H1 antihistamines, severity assessment (scoring instrument, biomarker, imaging, or biopsy as appropriate for the indication), prior therapy history including first-line options tried, and a clinical rationale for why Rhapsido is the appropriate next step given an oral covalent Bruton's tyrosine kinase (BTK) inhibitor that blocks mast-cell and B-cell activation.

The letter also specifies the exact dosing plan per the FDA-approved label: starting dose, maintenance dose, route of administration, schedule, and intended duration of therapy. Monitoring plan should reference any baseline laboratory or imaging requirements specific to Rhapsido (full blood count, liver function, infection screen, ophthalmology assessment, or pregnancy testing where the FDA label requires it), planned follow-up intervals, and dose-modification criteria for the most common adverse events.

The treating physician's Turkish license number, the dispensing facility license number, and the pharmacy in charge of dispensing complete the package. For cold-chain or specialty-handling products, the dispensing pharmacy's documented storage protocol and continuous-temperature-monitoring log are part of the chain-of-custody record we share with the importer.

Common questions about Rhapsido in Turkey

Will SGK public coverage with Allianz Sigorta, Anadolu Sigorta, and Acibadem Sigorta employer plans cover this? Each insurer assesses named-patient imports case by case. Some reimburse fully when Rhapsido is on their formulary even if not currently stocked, some reimburse a percentage subject to copay, and many require pre-authorisation. We supply the documentation set that allows your insurer to assess the case; the claim itself sits with you or your hospital.

Is the FDA-approved indication recognised by TITCK? The TITCK named-patient pathway exists precisely to permit access when the local registration or stocking lags the FDA label. The application documents the FDA indication, the reference-authority approval, and the local gap; TITCK review focuses on the clinical justification rather than re-litigating the FDA decision.

My physician is licensed in one emirate / state / province and the hospital is in another. Is that fine? Any Turkish-licensed physician practicing in good standing in the jurisdiction of the dispensing facility has signing authority on the clinical justification letter. The Turkish Medical Association (TTB) and the Ministry of Health licensing directorate verifies the active license; the TITCK application records both the prescribing physician and the dispensing facility.

Can I receive Rhapsido at home? The dispensing facility must be Turkish-licensed. The hospital outpatient or specialty pharmacy releases the medicine to you after final verification, and you then administer or self-administer at home where the FDA label permits, after the dispensing pharmacy's training. The cold-chain or controlled-storage handoff ends at the dispensing pharmacy; home storage and any handling protocol are part of your patient onboarding kit.

What about competitors or alternative therapies in the same class? Choice of therapy depends on the patient's full phenotype, prior therapy, and the prescriber's judgment. Reserve Meds coordinates whichever medicine the physician has prescribed; we do not substitute, advise on substitution, or promote one brand over another.

Where Reserve Meds fits in Rhapsido cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating physician, we do not replace TITCK, and we do not replace your dispensing pharmacy. For Rhapsido specifically, we orchestrate the US-side sourcing through a DSCSA-compliant specialty channel, build the documentation packet your physician submits, coordinate validated logistics (cold-chain with continuous temperature logging where the FDA label requires it) into Turkey, and assign a single named coordinator through the case. Standard named-patient coordination under our specialty playbook applies. Presentation selection, dose-band confirmation, and patient onboarding for self-administration where applicable are the recurring operational fundamentals we expect for this drug.

Operationally, a typical Rhapsido case runs across four parallel tracks. The clinical track is the physician's: justification letter, dosing plan, monitoring schedule, and the next patient-facing follow-up. The regulatory track is the TITCK application packaged by the importer; we provide the documentation template, the dispensing facility license check, and the chain-of-custody attestation. The logistics track is the US-side sourcing and the validated international shipment with continuous temperature logging and customs broker coordination. The patient-experience track is the named coordinator who keeps everyone aligned on dates, addresses dispensing-pharmacy questions, and confirms the medicine has been received and stored correctly. The four tracks are run in parallel rather than in series; that is the operational difference between a 3-week and a 9-week case.

Turkish tertiary specialty care for chronic spontaneous urticaria (dermatology and allergy / immunology scope) concentrates at Hacettepe University Hospital Dermatology in Ankara, Istanbul University Cerrahpasa Dermatology, and Acibadem Healthcare Group Dermatology in Istanbul; the TITCK named-patient supply pathway is routed through the Turkish Pharmacists Association (TEB) foreign medicines channel.

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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