> **Spevigo**
> Saudi Arabia · access guide

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

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

An Saudi Arabia patient with flares of generalised pustular psoriasis (GPP) in adults and paediatric patients aged 12 years and older and at least 40 kg may receive a prescription for Spevigo (spesolimab-sbzo) from their treating dermatologist with experience in inflammatory skin disease. Spevigo is FDA-approved in the United States and manufactured by Boehringer Ingelheim. It is a humanised IgG1 monoclonal antibody against the interleukin-36 receptor administered by intravenous infusion (flare) and subcutaneous (maintenance). Local availability of Spevigo in Saudi Arabia can be inconsistent: the drug may not be on every specialty pharmacy'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 SFDA 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

Spevigo is a humanised IgG1 monoclonal antibody against the interleukin-36 receptor. Mechanism: a humanised monoclonal antibody that blocks the IL-36 receptor and the downstream inflammatory cascade implicated in GPP. Dosing: a single 900 mg dose by intravenous infusion for flare, with an option for a second 900 mg dose one week later if flare persists; 600 mg subcutaneously for maintenance after the resolution dose, per FDA labeling. Baseline workup per FDA labeling includes infection screen including tuberculosis, hepatitis B and C serologies, liver function, and pregnancy testing where applicable. Other important warnings include infections including serious infections, hypersensitivity reactions including DRESS, and live-vaccine precautions. Your dermatologist will discuss the risk-benefit profile and schedule monitoring before initiating therapy.

Is Spevigo legally importable into Saudi Arabia?

Yes, through the Saudi Food and Drug Authority (SFDA) named-patient and personal-use import framework, coordinated through a Saudi Arabia-licensed treating facility's pharmacy. The Saudi Arabia has an established pathway for specialty medicines approved by reference authorities (US FDA, EMA, MHRA) but not stocked or registered for the specific indication locally.

The SFDA named-patient route allows an Saudi Arabia-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. Applications are typically filed through the dispensing institution's import pharmacy on the physician's behalf, with approval issued on a per-patient, per-cycle quantity basis.

How the pathway works, step by step

1. **Consultation with your treating dermatologist.** The prescribing decision is clinical. Your dermatologist documents the indication, prior therapies where relevant, and rationale for Spevigo.
2. **Baseline screening.** Infection screen including tuberculosis, hepatitis B and C serologies, liver function, and pregnancy testing where applicable are confirmed and documented.
3. **SFDA named-patient application.** Your dermatologist or the facility's import pharmacy files the application with clinical rationale, patient reference, product strength, 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 Boehringer Ingelheim's authorised distribution under DSCSA chain-of-custody.
5. **Cold-chain shipment.** Spevigo requires refrigerated transport at 2 to 8 degrees Celsius. Shipments include temperature-monitored packaging with continuous loggers and tamper-evident seals.
6. **Arrival and first dose.** The dispensing pharmacy releases product against the physician's prescription, and your dermatologist initiates therapy.

What documentation your physician needs

Your physician will typically need to provide:

- A clinical rationale letter confirming diagnosis, prior therapies where relevant, and Spevigo as the indicated next step
- Verification of their Saudi Arabia medical licence
- A patient identifier, anonymised reference where privacy is preferred
- Documented pre-treatment screening consistent with FDA labeling (see above)
- The planned dosing regimen (a single 900 mg dose by intravenous infusion for flare, with an option for a second 900 mg dose one week later if flare persists; 600 mg subcutaneously for maintenance after the resolution dose, per FDA labeling)
- A monitoring plan covering infection screen, GPP flare attestation, and storage and handling protocol

Reserve Meds provides a physician documentation kit tailored for GPP biologic therapies, including the templates SFDA reviewers commonly request.

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 single resolution dose (a confirmed flare typically requires one to two doses) of Spevigo sits in an indicative 2026 band of approximately USD 48,000 to 60,000. International logistics, SFDA documentation handling, cold-chain 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 2 to 5 weeks (faster for confirmed flare cases on physician attestation) from the moment a complete application is submitted, assuming the documentation package is clean on first pass. Refills ship on a rolling cadence aligned to the dosing schedule.

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 Spevigo 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 SFDA review, including GPP biologic class templates.
- **Cold-chain logistics.** Temperature-monitored, internationally tracked shipment to your named dispensing facility with continuous temperature loggers.
- **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 dermatologist, and dispensing sits with the licensed Saudi Arabia pharmacy of record. Reserve Meds operates on cash-pay only and does not bill insurance.

Frequently asked

Is this legal in Saudi Arabia? Yes, when executed through the SFDA named-patient and personal-use framework with appropriate documentation, clinical rationale, and a licensed dispensing facility. The pathway is routinely used across oncology, rare disease, and immunology at Saudi Arabia tertiary centers.

Will my private health insurance cover this? Cash-pay is the default posture. Some Saudi Arabia private insurers (Daman, AXA, Mednet-administered plans) reimburse named-patient 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.

How does cold-chain affect timing? Spevigo ships refrigerated. We use validated packaging with continuous temperature monitoring, and arrival temperature data is logged on every shipment.

What if my physician has not filed a named-patient request before? Named-patient import is an institutional process most major Saudi Arabia tertiary centers (Cleveland Clinic Abu Dhabi, Sheikh Shakhbout Medical City, American Hospital Dubai, and Mediclinic City Hospital) have encountered. Our documentation kit is written for first-time applicants and tracks what SFDA 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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