Winrevair

Bahrain · access guide

How to access Winrevair from Bahrain, the named-patient import pathway, 2026

By Reserve Meds · Clinical & regulatory team · Last reviewed 2026-04-24

A Bahrain adult with pulmonary arterial hypertension (PAH, WHO Group 1) may receive a prescription for Winrevair (sotatercept) from their treating pulmonologist or PAH specialist as add-on therapy to background PAH treatment. Winrevair is FDA-approved in the United States as the first activin signalling inhibitor for PAH, intended to improve exercise capacity, functional class, and reduce the risk of clinical worsening events when added to an existing PAH regimen. Because Winrevair is not yet routinely stocked in Bahrain hospital pharmacies, your specialist 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

Winrevair is a subcutaneous injection administered once every three weeks. It is a fusion protein that binds activins and related TGF-β superfamily ligands, rebalancing pro-proliferative and anti-proliferative signalling in the pulmonary vasculature. The manufacturer is Merck (developed by Acceleron). Eligibility rests on confirmed WHO Group 1 PAH, typically supported by right heart catheterisation, and current treatment with one or more PAH therapies (endothelin-receptor antagonist, PDE-5 inhibitor or soluble guanylate cyclase stimulator, and/or prostacyclin-pathway agent). Dosing is weight-based, starting at 0.3 mg/kg and escalating to a target of 0.7 mg/kg every three weeks. Monitoring includes haemoglobin (risk of erythrocytosis), platelets, and bleeding surveillance per FDA labeling.

Is Winrevair legally importable into Bahrain?

Yes, through the National Health Regulatory Authority (NHRA) named-patient import framework. The NHRA route allows a Bahrain-licensed physician to request import of a medicine that is not locally registered when: (a) the medicine has been approved by a recognised reference authority (FDA qualifies), (b) there is no clinically equivalent locally registered alternative, (c) the treating physician takes clinical responsibility, and (d) the importing party documents chain of custody. Applications are reviewed by the NHRA Drug Sector.

For PAH patients on optimised background therapy who remain intermediate- or high-risk, the clinical rationale for adding Winrevair is labeling-driven and straightforward to articulate.

How the pathway works, step by step

1. **Consultation with your treating PAH specialist.** Confirmation of WHO Group 1 PAH, right heart catheterisation documentation, current PAH regimen, risk stratification, and a written clinical rationale.
2. **Treatment-centre identification.** A Bahrain PAH-specialist service with infusion/injection training capability and haematology monitoring accepts the case.
3. **NHRA named-patient application.** Your physician or the hospital's importing pharmacy files the application including prescription, diagnostic documentation, background-regimen attestation, 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. **Cold-chain shipment.** Winrevair requires refrigerated handling and ships with validated cold-chain packaging and continuous temperature logging end to end.
6. **Arrival and initiation.** Your specialist starts therapy at the dose-titration schedule with in-clinic training for self- or caregiver-administered subcutaneous injections every three weeks. Reserve Meds coordinates the next cycle ahead of depletion.

What documentation your physician needs

Your physician will typically need to provide:

- A clinical rationale letter confirming WHO Group 1 PAH, right heart catheterisation findings, background PAH therapy, risk category, and Winrevair as the indicated add-on
- Verification of their Bahrain medical licence (SCFHS / MOH)
- A current prescription naming the product, weight-based dose, and every-three-week schedule
- Patient identifier (anonymised reference preferred)
- Planned monitoring cadence (haemoglobin, platelets, bleeding surveillance, clinical status)

Reserve Meds provides a physician documentation kit bundling the templates NHRA reviewers expect to see for cold-chain biologics under named-patient import.

Costs and timing

Winrevair's US cash-pay reference price for the every-three-week regimen sits in an indicative 2026 annualised range of roughly USD 240,000-280,000 for a typical adult at target dose. Cold-chain logistics, NHRA documentation handling, and concierge coordination add incremental cost; Reserve Meds issues a full transparent quote at the start of intake, with a drug-only reference figure separated from service charges.

Indicative timing for first shipment arrival after cohort intake opens is 7-14 days from the moment a complete NHRA application is submitted. Subsequent cycles are scheduled to match the every-three-week calendar.

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.

A culturally-aware note: Ramadan and Hajj seasons can affect injection-schedule adherence. Our concierge team coordinates cycle timing with your family's preferences and your specialist's calendar.

Reserve Meds's role

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Winrevair 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 NHRA review, including PAH diagnostic-attestation templates.
- **Logistics.** Cold-chain shipment and chain-of-custody coordination with temperature logging.
- **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 PAH specialist.

Frequently asked

Is this legal in Bahrain? Yes, when executed through the NHRA named-patient framework with appropriate documentation. See our trust and compliance page.

Is Winrevair a replacement for my current PAH regimen? No. Winrevair is labeled as add-on therapy. Your existing PAH medications continue, and your specialist adjusts the regimen as clinically appropriate.

What is the erythrocytosis risk? Haemoglobin can rise on Winrevair, and the label mandates periodic monitoring with dose adjustment or therapeutic phlebotomy if needed. Your specialist manages this proactively.

Can I self-inject? After in-clinic training, many patients or caregivers can administer the subcutaneous injection at home every three weeks. Your specialist decides when self-administration is appropriate.

Will private insurance cover this? Cash-pay is the default. Some Bahrain private insurers reimburse named-patient imports of PAH therapies on a case-by-case basis; 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.

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