Winrevair access in Saudi Arabia via the SFDA named-patient pathway

How patients in the Kingdom of Saudi Arabia obtain Winrevair (sotatercept-csrk) as add-on therapy for pulmonary arterial hypertension, through the Saudi Food and Drug Authority Personal Importation Program.

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

1. Quick orientation

Winrevair is the brand name for sotatercept-csrk, a first-in-class activin signaling inhibitor approved by the US Food and Drug Administration on March 26, 2024 for the treatment of adults with pulmonary arterial hypertension (PAH, WHO Group 1). The October 2025 label update added reduction of clinical worsening events, including PAH hospitalization, lung transplantation, and death. Winrevair is an add-on biologic dosed subcutaneously every three weeks, intended to layer on top of existing PAH therapy rather than replace it. For patients in Saudi Arabia whose PAH specialist wants Winrevair as add-on therapy while the drug works through local registration and stocking, the Saudi Food and Drug Authority (SFDA) Personal Importation Program (PIP) is the lawful, documented route. Reserve Meds is the US-side coordinator that aligns the sourcing, the cold-chain logistics, and the regulatory documentation kit your treating physician needs. Reserved for you.

2. Why patients in Saudi Arabia need Winrevair via NPP

Pulmonary arterial hypertension is a rare, progressive, life-limiting disease, and Winrevair represents a mechanistically novel addition to a therapeutic class that had not seen a first-in-class entrant in many years. International registration is incomplete, and even where registration is in place at the regulatory level, routine stocking through hospital formularies, national reimbursement, and commercial distribution chains lags the regulatory timeline. The pattern in Saudi Arabia matches the broader MENA picture: patients identified at expert PAH centers in Riyadh and Jeddah whose treating physicians want Winrevair as add-on therapy often find that the product is not yet routinely stocked at the receiving institution, even where SFDA registration is pending or recent.

Saudi Vision 2030 and the Health Sector Transformation Program (HSTP) are expanding tertiary cardiopulmonary care across Riyadh, Jeddah, and the Eastern Province, surfacing more PAH patients who reach the point where a treating PAH specialist wants to add an activin-pathway agent to a background regimen of endothelin receptor antagonists, PDE-5 inhibitors or guanylate cyclase stimulators, and prostacyclin pathway agents. For these patients, the absence of a clinically equivalent locally registered alternative in the same mechanistic class is exactly the condition the PIP framework was designed for.

Reserve Meds positions Winrevair as a Tier-1 access case where cold-chain discipline at 2 to 8 degrees Celsius, multi-shipment cadence planning for the every-three-week dosing rhythm, and destination-physician readiness for hemoglobin and platelet monitoring are the operational drivers that distinguish a clean PAH access cycle.

3. The SFDA Personal Importation Program for Winrevair

The SFDA Personal Importation Program allows a KSA-licensed physician to request import of a specific medicine for a specific named patient when the medicine is approved by a recognized reference authority (US FDA and EMA for Winrevair) and a clinically equivalent locally registered alternative is not suitable. The framework explicitly contemplates rare disease and specialty cardiovascular and pulmonary therapies. Applications are filed through the dispensing institution's

import pharmacy and reviewed by SFDA's Drug Sector, with named-patient activity increasingly routed through the agency's Ghad digital regulatory platform.

For Winrevair specifically, the application package contains:

- **Clinical justification letter** from the treating PAH specialist, addressing diagnosis with ICD-10 coding (I27.0 for primary pulmonary hypertension or I27.20 to I27.29 for secondary PAH subtypes), WHO Group 1 confirmation with right-heart catheterization data where available, WHO functional class, the background PAH regimen and its outcomes, the rationale for adding an activin signaling inhibitor, and the requested dose-titration plan.
- **SCFHS licensure verification** in pulmonary medicine, cardiology, or a related specialty appropriate to manage PAH and Winrevair-specific monitoring.
- **Baseline hemoglobin and platelet documentation.** The FDA label requires assessment before each dose because increases in hemoglobin and reductions in platelets are recognized class effects, and the PIP file should reflect that this monitoring is in place at the destination institution.
- **Patient identifier** in the format SFDA requires, typically an anonymized internal reference linked to the national ID inside the hospital record.
- **Product details** including brand name (Winrevair), international nonproprietary name (sotatercept-csrk), manufacturer (Merck & Co., Inc.), country of origin (USA), strength (45 mg or 60 mg single-dose vial as lyophilized cake), kit composition with pre-filled sterile water diluent, requested quantity, lot, and expiry.
- **Destination dispensing facility license** showing the receiving pharmacy is SFDA-licensed to handle imported biologics with cold-chain storage.
- **Chain-of-custody plan** from the US specialty pharmacy (Accredo or CVS Specialty under Merck's named distribution) through international transit with validated 2 to 8 degree Celsius packaging, continuous temperature monitoring, and light-protective handling, to the receiving Saudi pharmacy, including freight forwarder, customs broker, and importer of record.

Approval timelines for routine cases typically run 10 to 21 business days. First-time Winrevair imports at an institution can extend toward the 6 to 10 week range while internal committees and the importer onboard a new biologic. SFDA does not publish guaranteed turnaround times.

4. Where Winrevair gets dispensed in Saudi Arabia

Winrevair is a refrigerated lyophilized biologic that, after reconstitution, is administered subcutaneously rather than by IV infusion. Eligible patients or caregivers may self-administer at home after training by a healthcare professional, but the case workup, the first doses, the hemoglobin and platelet monitoring, and the cold-chain receipt sit at a PAH expert center. In Saudi Arabia, the institutions with the PAH specialist coverage and the import pharmacy infrastructure to handle Winrevair cases include King Faisal Specialist Hospital and Research Centre (KFSH&RC) in Riyadh and Jeddah, King Abdulaziz Medical City (KAMC) and the Ministry of National Guard Health Affairs (MNGHA) network, King Saud University Medical City (KSUMC) and KSAU-HS affiliated centers, the Dr. Sulaiman Al Habib Medical Group (HMG) network, Saudi German Health facilities, Dr. Soliman Fakeeh Hospital in Jeddah, and Dallah Hospital in Riyadh.

Smaller hospitals without internal import pharmacy capacity typically route Winrevair cases through one of these centers, or through an SFDA-licensed specialty importer based in Riyadh or Jeddah who handles the SFDA filing, the chain-of-custody documentation, and the customs clearance under the destination facility's institutional license.

5. Real cost picture for Winrevair in Saudi Arabia

Three line items make up the patient-facing cost of a Winrevair case sourced from the United States into Saudi Arabia.

Drug acquisition. US wholesale acquisition cost (WAC) published by Merck for Winrevair sits at approximately USD 14,000 per single-dose vial, with the 45 mg kit (containing two single-dose vials) reported at roughly USD 29,705 in state pricing transparency filings. The reported annualized US list price for full target-dose therapy in an adult patient is approximately USD 240,000 per year, which translates to roughly SAR 900,000 per year at WAC reference, scaling with patient weight (0.7 mg/kg target dose every 3 weeks) and the vial-strength combination used to deliver the prescribed dose.

International logistics surcharge. Validated 2 to 8 degree Celsius shipping with continuous temperature monitoring and light-protective packaging, plus customs documentation and importer-of-record handling, typically adds SAR 3,000 to SAR 9,000 per shipment. Because dosing is every three weeks on a chronic basis, Reserve Meds plans repeat-shipment cadence at the case-acceptance stage rather than treating each shipment as a one-off.

Coordination, documentation, and concierge fee. Reserve Meds quotes the concierge fee transparently on every case, with the rate disclosed on the firm quote. The fee covers documentation kit preparation, US sourcing through Merck's authorized specialty channel, cold-chain orchestration, customs paperwork, and a single named coordinator from intake through reorders.

Local PAH specialist visits, baseline and ongoing hemoglobin and platelet monitoring, right-heart catheterization or echocardiography, and self-injection training are billed by the receiving Saudi institution and are not part of the Reserve Meds quote. Local insurer behavior on Winrevair varies. Bupa Arabia, Tawuniya, and MedGulf each handle named-patient imports case-by-case under the Council of Cooperative Health Insurance (CCHI) framework, with pre-authorization typically required and reimbursement, where available, often coming after the fact through the patient's own claim.

6. Typical timeline for Winrevair in Saudi Arabia

From the date the clinical justification letter is signed and the PIP file is submitted, routine SFDA review for Winrevair typically runs 10 to 21 business days. First-time Winrevair imports at an institution can extend toward the 6 to 10 week range while pharmacy committees and the importer onboard a new biologic with cold-chain handling. Cold-chain transit adds approximately 2 to 3 days versus ambient air freight. After the initial dose, the every-three-week dosing cadence sets the rhythm: each reorder window opens roughly three to four weeks before the next dose to allow procurement, transit, customs, and pharmacy receipt without compressing the dosing interval, and Reserve Meds plans the multi-dose sourcing schedule at case acceptance.

7. What your physician needs to provide

The clinical justification letter is the cornerstone of the SFDA submission. For a Winrevair PIP application, the letter typically covers the following.

- **Diagnosis and classification.** WHO Group 1 PAH with right-heart catheterization confirmation where available, WHO functional class II or III as the FDA-labeled population, and the etiology subtype.
- **Background regimen.** The patient's existing PAH regimen, including endothelin receptor antagonist, PDE-5 inhibitor or guanylate cyclase stimulator, and any prostacyclin pathway agents, with the duration on each and the clinical response.
- **Rationale for add-on therapy.** Why the treating PAH specialist judges the patient remains symptomatic, functionally limited, or at elevated risk despite the background regimen, in line with the FDA-labeled indication for Winrevair as add-on therapy.
- **Dosing plan.** Starting dose at 0.3 mg/kg subcutaneously, with dose escalation to the target maintenance dose of 0.7 mg/kg every 3 weeks if tolerated, and the appropriate vial-strength selection (45 mg or 60 mg) to deliver the prescribed milligram dose with the smallest practical injection volume.

- **Monitoring plan.** Hemoglobin and platelet counts assessed before each dose, with the label-defined thresholds for dose interruption, dose reduction, or discontinuation documented in the plan. Blood pressure monitoring and surveillance for injection-site reactions, telangiectasia, and epistaxis as adverse events of interest.
- **Adverse-event reporting commitment.** The treating physician's commitment to report any adverse event through the SFDA National Pharmacovigilance Center, signed under the SCFHS license.

Reserve Meds supplies a documentation kit that maps each of these elements to the SFDA-required sections, so the physician is not building the file from scratch.

8. Common questions about Winrevair in Saudi Arabia

Will Bupa Arabia, Tawuniya, or MedGulf cover Winrevair? Each plan handles named-patient imports case-by-case under CCHI rules. Some plans reimburse fully when the medicine appears on the insurer's formulary; others reimburse a percentage; many require pre-authorization with the clinical justification letter attached. Cash-pay is the default operating posture, with reimbursement sought after delivery if the plan permits.

Can a Ministry of Health PAH specialist sign the PIP letter? Yes. KSA-licensed physicians at Ministry of Health hospitals, KFSH&RC, KAMC, MNGHA, and other public-sector institutions have full signing authority on PIP applications under their SCFHS license, as do private-sector physicians at HMG, Saudi German, Fakeeh, Dallah, and similar institutions.

Can Winrevair be self-administered at home? After training by a healthcare professional, eligible patients or caregivers may self-administer Winrevair subcutaneously at home. The first doses are typically given under clinical supervision. The drug arrives at the dispensing facility under the chain-of-custody plan, where the patient or caregiver receives it for home administration once self-injection training is complete.

What is the safety profile? Adverse events reported more frequently with Winrevair than placebo in the STELLAR trial included epistaxis, telangiectasia, dizziness, increased hemoglobin, thrombocytopenia, and increased blood pressure. Injection-site reactions are also documented. The full safety profile, warnings, and precautions are in the FDA label.

What is the monitoring requirement? Hemoglobin and platelet counts are assessed before each dose, with label-defined thresholds for dose interruption or modification. Ongoing specialist supervision by a PAH-experienced physician is expected.

Is there a comparator? Winrevair is the only approved drug in its mechanistic class (activin signaling inhibition) for PAH. Other PAH therapies operate via different mechanisms and are typically continued as background therapy alongside Winrevair rather than replaced by it. The decision to add Winrevair is clinical and individual, made by the treating PAH specialist.

9. Where Reserve Meds fits in Winrevair cases

Reserve Meds has no prior Saudi Winrevair case experience as of the review date. Standard NPP coordination applies, with three operational notes specific to this product: validated 2 to 8 degree Celsius cold-chain across multi-leg transit with light-protective packaging; pre-planned multi-dose shipment cadence aligned to the every-three-week dosing rhythm; and a US sourcing path through Merck's authorized specialty channel rather than open wholesale. The clinical decisions remain with the SCFHS-licensed PAH specialist. The regulatory authority remains SFDA. The dispensing remains with the licensed Saudi pharmacy. Reserve Meds is the connective tissue between the US specialty pharmacy and those three Saudi pillars, with a single named coordinator who stays with the case through reorders.

10. Next step

If your treating PAH specialist in Saudi Arabia has identified Winrevair as the right add-on therapy and you are ready to start the PIP file, the next step is to add your case to the waitlist so Reserve Meds can confirm eligibility within 24 to 48 hours and send the documentation kit to your physician.

Reserved for you.

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