

[Skip to main content](#)

[Home](#) / [Drugs](#) / [Winrevair](#) / [In UAE](#)

Winrevair access in the UAE: the MOHAP and EDE named-patient pathway

How patients with pulmonary arterial hypertension in the UAE legally obtain Winrevair (sotatercept-csrk) from US-source supply when the medicine is not yet stocked or registered locally.

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

Quick orientation

Winrevair (sotatercept-csrk) is a first-in-class activin signaling inhibitor approved by the US FDA in March 2024 for adults with pulmonary arterial hypertension (PAH, WHO Group 1). It is administered as a subcutaneous injection every three weeks, used as an add-on to background PAH therapy rather than as monotherapy. In the United Arab Emirates, Winrevair is not yet routinely stocked. Patients identified at expert PAH centers across Abu Dhabi and Dubai whose treating pulmonologists want sotatercept as add-on therapy reach the medicine through the unregistered-medicine import permit administered by the Ministry of Health and Prevention (MOHAP) and, from 29 December 2025, through the Emirates Drug Establishment (EDE) portal. Reserve Meds handles the US-side specialty pharmacy sourcing and the cold-chain logistics.

Reserved for you.

Why UAE patients need Winrevair via the named-patient pathway

The UAE federal regulatory environment is one of the most developed in the Gulf, with MOHAP holding the national drug register and the EDE assuming 44 core services from December 2025. Even with this maturity, UAE PAH patients face three structural access gaps. The drug may be on a manufacturer's registration roadmap but not yet on the federal register, it may be registered but not stocked at the specific pulmonary hypertension center where the patient is being followed, or local formulary timelines and importation lead times may not match the clinical urgency of a patient who remains symptomatic despite combination background therapy.

Winrevair's profile reinforces the case for the pathway. PAH is rare, progressive, and life-limiting, and Winrevair is the first mechanistically novel addition to the PAH class in many years. International registration has progressed quickly through the EMA (August 2024) and UK MHRA, but Middle East registration and routine commercial stocking through national health systems and private hospitals lag US and EU availability. Even in markets where Winrevair is registered, local pricing, importation, or formulary pathways often make timely access impractical for a patient whose treating PAH specialist has clinically determined that add-on therapy is required now. Cash-pay named-patient sourcing through the EDE pathway is the recognised regulatory route for these cases.

The MOHAP and EDE named-patient pathway for Winrevair

The federal pathway for a UAE-licensed physician to obtain a medicine that is not registered or not stocked locally is the unregistered-medicine import permit. Historically administered by MOHAP and from 29 December 2025 administered through the EDE portal at ede.gov.ae under Federal Decree-Law No. 38 of 2024, the framework allows hospitals and licensed pharmaceutical establishments to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority (US FDA, EMA, MHRA, PMDA Japan, Health Canada) and a clinically equivalent locally registered alternative is not suitable. PAH, as a progressive life-limiting disease, sits squarely within the compassionate-use framework the UAE legal architecture contemplates.

A complete Winrevair application typically includes:

- A clinical justification letter from the treating pulmonologist (PAH diagnosis with WHO Group 1 confirmation, WHO functional class, right heart catheterisation findings where available, current background PAH regimen, rationale for adding Winrevair as the next therapeutic step)
- The treating physician's UAE medical license verification (MOHAP, DHA, DOH, or Sharjah Health Authority, matched to the dispensing facility's emirate)
- A patient identifier (anonymised reference is preferred where the EDE submission allows)
- Full product details: Winrevair (sotatercept-csrk), Merck and Co. Inc., 45 mg or 60 mg single-dose vial kits with diluent, quantity tied to the 0.3 mg/kg starting dose escalating to 0.7 mg/kg every three weeks at the patient's weight
- The destination dispensing facility (typically the PAH center's hospital pharmacy or a specialty importer's bonded warehouse for onward delivery to the center)
- A chain-of-custody plan describing how Winrevair will move from the US specialty pharmacy (Accredo or CVS Specialty) through the importer to the dispensing facility under continuous 2 to 8 degree Celsius cold chain, with light-protective packaging and continuous temperature monitoring

For Winrevair, the clinical justification letter benefits from documentation that adds two specific elements beyond a generic PAH narrative: baseline hemoglobin and platelet counts (because increases in hemoglobin and reductions in platelets are recognized class effects with label-defined dose-interruption thresholds), and the planned monitoring cadence by which the prescribing PAH specialist will assess each pre-dose. Approval timelines for routine UAE cases are typically 5 to 15 business days. First-time imports of a novel-mechanism biologic at a given center can extend to 4 to 6 weeks.

Where Winrevair gets dispensed in the UAE

Winrevair is a subcutaneous injection that is reconstituted at the time of use and, after training by a healthcare professional, can be self-administered by the patient or caregiver at home. The first doses are typically given under clinical supervision at the prescribing PAH center. The UAE institutions that handle PAH and named-patient imports as established workflow include Cleveland Clinic Abu Dhabi (the M42 group's 364-bed multispecialty hospital, with complex cardiology), Sheikh Khalifa Medical City in Abu Dhabi (the SEHA network's 586-bed JCI-accredited tertiary center), and American Hospital Dubai (Mayo Clinic Care Network member). King's College Hospital London Dubai and Mediclinic City Hospital in Dubai Healthcare City carry adult cardiology and pulmonary services. Tawam Hospital in Al Ain and the larger NMC Healthcare sites hold pharmaceutical establishment licenses and can route the import directly.

For families in the Northern Emirates without a local PAH specialty center, the practical pattern is to route to a Dubai or Abu Dhabi PAH center where the treating pulmonologist holds privileges. The first injection-and-training visit is performed at the PAH center; subsequent every-three-week doses can be administered at home by the patient or caregiver after training, with the PAH center holding the case under specialist supervision.

Real cost picture for Winrevair in the UAE

The UAE dirham is pegged to the US dollar at approximately 3.67 AED to 1 USD. The US wholesale acquisition cost 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) 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 (approximately AED 880,000), before any rebates, discounts, or assistance programs that the US-only Merck Access Program might apply.

International logistics for a refrigerated biologic kit with continuous temperature monitoring typically runs USD 600 to 1,500 (approximately AED 2,200 to 5,500) per shipment, depending on the destination emirate and urgency window. UAE customs and EDE permit fees are nominal relative to the drug cost. Reserve Meds itemises the US-side specialty pharmacy

procurement, the international cold-chain logistics, and the concierge coordination fee separately on every firm quote. On the insurance side, Daman National Health Insurance (the largest insur