Winrevair access in Egypt: the EDA Personal Importation pathway

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

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Quick orientation

Winrevair (sotatercept-csrk) is a first-in-class activin signaling inhibitor approved by the US Food and Drug Administration in March 2024 for adults with pulmonary arterial hypertension (WHO Group 1), used as add-on therapy to background PAH treatment. In October 2025 the FDA expanded the label to include reduction in risk of clinical worsening events. In Egypt, Winrevair has not yet been registered or routinely stocked. Patients followed at specialist PAH centres whose treating cardiologists want sotatercept as add-on therapy reach the medicine through the Egyptian Drug Authority (EDA) Personal Importation pathway under Law No. 151 of 2019. An Egyptian-licensed cardiologist or pulmonologist with PAH expertise files the application through a licensed dispensing hospital. Reserve Meds handles the US-side sourcing, cold-chain logistics, and the documentation kit your physician needs.

Reserved for you.

Why patients in Egypt need Winrevair via the named-patient pathway

PAH 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 for many years. In Egypt, the access gap shows up in three structural patterns. Winrevair may not yet appear on the EDA register, because the manufacturer's regional registration plan trails the US launch. It may be on the register but with no functioning local importer's shelf inventory, because the patient population is small and the local margin is thin. Or the available quantity at a particular tertiary cardiology centre cannot meet the chronic every-3-week dosing cadence the regimen requires. The 2018 Universal Health Insurance Law is expanding public coverage in stages, but cardiology specialty imports for PAH remain dominated by cash-pay families, often with USD funds coordinated from relatives in the Gulf.

Winrevair's own profile reinforces why the named-patient pathway is the practical route. The European Medicines Agency granted marketing authorisation in August 2024 and the UK MHRA followed, but in MENA, South Asia, and other emerging markets local approval, importation licensing, and routine commercial stocking through national health systems and private hospitals lag behind US and EU availability. The PAH population in Egypt is small but identified at expert centres. The drug is the only approved activin signaling inhibitor and has no therapeutically equivalent local substitute. For patients remaining symptomatic on optimised background therapy (endothelin receptor antagonists, PDE-5 inhibitors or guanylate cyclase stimulators, and prostacyclin pathway agents), the documented Personal Importation route is the legal access path.

The EDA named-patient pathway for Winrevair

The Egyptian Drug Authority was created by Law No. 151 of 2019. EDA is a public service authority affiliated to the Prime Minister that consolidates functions previously held by NODCAR, NORCB, and the Ministry of Health's Central Administration of Pharmaceutical Affairs. The EDA Drug Registration Sector handles registration files, and the Egyptian Pharmacovigilance Center (EPVC) handles post-market safety. EDA permits importation of unregistered medicines for a

specific patient where no equivalent registered product is available locally or where the available quantity cannot meet the patient's clinical need. The pathway is commonly referred to as Personal Importation. The application is filed through the dispensing institution's import pharmacy, typically a private specialty hospital, a university hospital import desk, or a licensed specialty importer.

A complete Winrevair application typically includes:

- A clinical justification letter from the treating PAH-experienced cardiologist or pulmonologist, original, stamped, on hospital letterhead, stating the diagnosis of WHO Group 1 PAH, WHO functional class, prior PAH therapies and current background regimen, why Winrevair is the appropriate add-on, and the patient's most recent right heart catheterisation or echocardiographic assessment
- The treating physician's Egyptian Medical Syndicate membership number and Ministry of Health licence reference
- A recent prescription specifying brand name (Winrevair), generic name (sotatercept-csrk), and the weight-based dosing plan (starting 0.3 mg/kg subcutaneous every 3 weeks, escalating to target 0.7 mg/kg if tolerated) with the appropriate 45 mg or 60 mg single-dose kit
- A patient identifier (national ID or passport copy)
- Product details: Merck & Co., Inc., country of origin, FDA approval reference, shelf life, and the 2 to 8 degree Celsius storage condition
- The destination dispensing facility licence number
- A chain-of-custody plan describing how Winrevair will move under continuous 2 to 8 degree Celsius cold chain from a US specialty pharmacy (Accredo or CVS Specialty) through air freight to Cairo International Airport with documented temperature logging at every handoff

For Winrevair, the clinical justification letter benefits from explicit documentation of WHO Group 1 PAH diagnosis (excluding Group 2, 3, 4, or 5 pulmonary hypertension, which are not in label), the patient's baseline hemoglobin and platelet count (because increases in hemoglobin and reductions in platelets are recognised class effects requiring monitoring before each dose), the background PAH regimen (Winrevair is add-on, not monotherapy), and the proposed home-administration plan after initial supervised dosing. Routine EDA personal-import authorisations for well-documented rare-cardiology cases are typically processed in 3 to 6 week windows, with complex first-time biologic imports potentially extending to 8 to 14 weeks. EDA reserves discretion at every step.

Where Winrevair gets dispensed in Egypt

Winrevair requires PAH expert supervision at initiation, with the ability to manage hematology monitoring at every 3-week dose interval, plus patient training on subcutaneous self-administration after the first doses are given under clinical supervision. The Egyptian institutions that fit this profile and routinely handle named-patient specialty imports include Magdi Yacoub Heart Foundation, the leading cardiovascular surgical and pulmonary hypertension centre in Egypt, with import experience for advanced cardiology therapies; Cairo University Hospitals (Kasr Al Ainy), the oldest and largest academic hospital network in Egypt and the Middle East, with a Drug Information Center and dedicated cardiology and rare-disease units; Ain Shams University Hospitals, the second major academic hospital network in Cairo; As-Salam International Hospital in Cairo, the first hospital in the Middle East to earn JCI Clinical Care Certification for Acute Myocardial Infarction; Dar Al Fouad Hospital in 6th of October City, JCI-accredited and with a long-standing Cleveland Clinic cooperation; and the Cleopatra Hospitals Group, the largest private hospital group in Egypt.

For families outside the Cairo and Giza corridor, the practical pattern is co-management between a regional cardiology team and a Cairo-based PAH expert centre, with the dispensing facility licence