Winrevair access in India: the CDSCO Rule 36 named-patient pathway

How adults in India with pulmonary arterial hypertension legally obtain Winrevair (sotatercept-csrk) from US-source supply through CDSCO personal importation, with validated cold-chain logistics and PAH-center coordination built into the case plan.

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Quick orientation

Winrevair (sotatercept-csrk) is a first-in-class activin signaling inhibitor approved by the US FDA on 26 March 2024 for the treatment of adults with pulmonary arterial hypertension (PAH, WHO Group 1) to increase exercise capacity and improve WHO functional class. In October 2025 the FDA updated the label, based on the Phase 3 ZENITH study, to include reduction of the risk of clinical worsening events including hospitalization for PAH, lung transplantation, and death. It is administered as a subcutaneous injection every three weeks as add-on to background PAH therapy. Indian commercial stocking and routine reimbursement of Winrevair lag US and EU availability, and PAH patients at Indian expert centres reach the medicine through the Central Drugs Standard Control Organization (CDSCO) personal importation framework under Rule 36 of the Drugs and Cosmetics Rules 1945, with Form 12A application and Form 12B permit issued by the Drugs Controller General of India (DCGI). Reserve Meds coordinates the US-side specialty pharmacy sourcing through Accredo or CVS Specialty under DSCSA serialization, the validated 2 to 8 degree Celsius cold-chain logistics, and the documentation kit your PAH specialist needs to file.

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

India's PAH clinical infrastructure has matured. Dedicated pulmonary hypertension programmes operate at AIIMS New Delhi, the cardiology and pulmonology services at Apollo (Chennai flagship, Delhi, Bangalore, Hyderabad), Fortis Escorts and Fortis Memorial Research Institute Gurgaon, Medanta The Medicity, Kokilaben Mumbai, MGM Healthcare Chennai, CMC Vellore, and Manipal Bangalore. Treating physicians at these centres routinely prescribe combinations of endothelin receptor antagonists, PDE-5 inhibitors or guanylate cyclase stimulators, and prostacyclin-pathway agents as background therapy. What is missing for many patients is a routinely stocked first-in-class activin-pathway inhibitor as an add-on option.

Three structural patterns drive the access gap for Winrevair specifically. First, registration timing: outside the US and EU, Winrevair is at an earlier stage in many Asian and Middle Eastern jurisdictions, with local approval, importation licensing, and routine commercial stocking lagging. Second, limited US specialty distribution: Merck has named Accredo Specialty Pharmacy and CVS Specialty as the two designated US dispensing channels, which means there is no broad retail or wholesale presence and inventory visibility outside those channels is limited. Third, PAH urgency: patients remaining symptomatic, functionally limited, or at elevated risk despite standard combination regimens are the population for whom add-on Winrevair changes the trajectory. The ZENITH data update extended the indication to include clinical-worsening reduction. The clinical case for timely access is not academic. The Rule 36 framework is the legal route, and routine cases at expert PAH centres move quickly when documentation is complete.

The CDSCO Rule 36 named-patient pathway for Winrevair

The legal foundation for personal import of an unregistered medicine into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits the import of a small quantity of a drug, whose import would otherwise be prohibited under Section 10 of the Drugs and Cosmetics Act 1940, for the exclusive personal use of a named patient. Form 12A is the application for the permit. Form 12B is the permit itself, issued by the office of the DCGI at FDA Bhawan, Kotla Road, New Delhi, or by designated CDSCO Port Offices. The application is accompanied by a prescription from a Registered Medical Practitioner (RMP) showing the RMP's National Medical Commission (NMC) registration number and the quantity required for treatment. The quantity of any single drug imported is capped at one hundred average doses per application, which for Winrevair's every-three-week dosing covers a substantial supply window per filing.

For institutional Compassionate Use of drugs not approved for marketing in India at all, the parallel pathway is the Compassionate Use application route to the DCGI by a government hospital, a registered medical practitioner, a pharmaceutical company, or the patient. This route applies when the drug is approved by a recognised reference authority (FDA, EMA, MHRA, Health Canada, PMDA) for a life-threatening condition, a serious permanent disability, or an unmet medical need. PAH WHO Group 1 fits that framing on the unmet-need axis.

For Winrevair specifically, the clinical-justification angle is precise. The strongest Form 12A applications consistently document: a pulmonologist-confirmed or cardiologist-confirmed diagnosis of pulmonary arterial hypertension WHO Group 1 with right-heart catheterisation hemodynamics, vasoreactivity status where measured, and the current WHO functional class; the patient's current background PAH regimen (endothelin receptor antagonist, PDE-5 inhibitor or guanylate cyclase stimulator, prostacyclin-pathway agent as applicable) with documented continuing symptoms or risk-stratification justifying add-on therapy; the proposed Winrevair dosing plan starting at 0.3 mg/kg subcutaneous every three weeks with planned escalation to the 0.7 mg/kg target maintenance dose if tolerated; and the pre-dose monitoring plan for hemoglobin and platelet count thresholds per the FDA label. CDSCO's published guidance states Form 12B is typically issued within one to two business days for routine applications where documentation is complete. Indian families and PAH centres plan for a two to four week window from specialist decision to first injection, with the elapsed time dominated by upstream documentation assembly and downstream cold-chain logistics rather than the regulator's stamp.

Where Winrevair gets dispensed in India

Winrevair is supplied as a kit containing the lyophilised drug vial (45 mg or 60 mg), a pre-filled syringe of sterile water for injection as diluent, and supplies for subcutaneous administration. Storage class is refrigerated cold chain at 2 to 8 degree Celsius in the original carton, protected from light. After reconstitution to a final concentration of 50 mg/mL the product should be used as soon as possible and no later than four hours after reconstitution. After healthcare-professional training on reconstitution and subcutaneous injection technique, eligible patients or caregivers may self-administer Winrevair at home; the first doses are typically given under clinical supervision.

The Indian institutions with established PAH clinical programmes, the cold-chain storage infrastructure, and the case workflow to support a Rule 36 import of Winrevair include AIIMS New Delhi (apex public-sector institution with pulmonary hypertension expertise), Apollo Hospitals (Chennai flagship, Delhi, Bangalore, Hyderabad), Fortis Healthcare (Fortis Escorts and Fortis Memorial Research Institute Gurgaon), Medanta The Medicity, Kokilaben Dhirubhai Ambani Hospital Mumbai, MGM Healthcare Chennai, Christian Medical College (CMC) Vellore, and Manipal Hospitals Bangalore. For patients in smaller cities without a dedicated PAH programme, the practical pattern is to route the case to one of the centres above for the initial dose escalation and monitoring, or to work through a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore that handles the Form 12A filing for a home-administration patient.

Real cost picture for Winrevair in India

Costs sit in Indian rupees with the rupee floating against the US dollar. In May 2026 the USD/INR rate is in the 94 to 95 range. The 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 (two single-dose vials) reported at roughly USD 29,705 in state pricing transparency

filings. Reported annualised US list price for full target-dose therapy in an adult patient is approximately USD 240,000 per year, before any rebates, discounts, or US-only assistance programs. At the prevailing USD/INR rate, the annualised US drug cost converts to approximately INR 2.25 crore per year before India-side logistics, hospital training visits, and laboratory monitoring (CBC every dose).

International validated 2 to 8 degree Celsius cold-chain shipping for the every-three-week dosing cadence typically runs USD 400 to 1,200 per shipment depending on city of destination, urgency window, and whether multiple cycles are consolidated. CDSCO permit fees are nominal relative to the drug cost. India's Union Budget 2026-27 expanded customs-duty exemption on a set of named life-saving and rare-disease drugs; the specific HSN code and exemption status of each Winrevair shipment is confirmed at the documentation stage. GST on most life-saving medicines is 5 percent.

None of the major Indian private insurers (Star Health and Allied Insurance, HDFC ERGO, ICICI Lombard, Apollo Munich, Niva Bupa) reimburse a Rule 36 personal import as a standard line item. The PAH category attracts insurer interest because it is a chronic, progressive, life-limiting condition with a defined specialist pathway, and several plans have considered case-by-case reimbursement when the underlying medicine is on their formulary and the import route is a stocking workaround. Reserve Meds itemises US-side procurement, international cold-chain logistics, and concierge coordination separately on every firm quote to give the insurer or the hospital a clean documentation record to evaluate against. Cash-pay is the operating default. The National Policy for Rare Diseases (NPRD) 2021 financial-assistance ceiling of INR 50 lakh per patient is structured around one-time treatments and does not align with the indefinite chronic dosing of Winrevair, but Centre-of-Excellence-anchored cases occasionally find partial support.

Typical timeline for Winrevair in India

For a routine Indian Winrevair case, the CDSCO Form 12B permit window is typically one to two business days from a complete Form 12A filing. The cold-chain biologic class adds two to three days to international transit windows compared with ambient products. Validated 2 to 8 degree Celsius shipping is rated for 72 to 120 hours, which dictates route selection and customs-clearance timing at Delhi, Mumbai, Bengaluru, Chennai, or Hyderabad airports. First-time imports at a PAH centre that has not previously stocked Winrevair can add one to two weeks for institutional pharmacy onboarding and confirmation of training capacity for self-administration. Because Winrevair is dosed every three weeks on an indefinite chronic basis, Reserve Meds plans repeat-shipment cadence at case acceptance and quotes patients for an initial sourcing window with the understanding that ongoing access is re-quoted as treatment continues.

What your physician needs to provide

The clinical justification letter is the cornerstone of the Form 12A filing. For Winrevair, the strongest letters consistently include: a PAH specialist's confirmed diagnosis of pulmonary arterial hypertension WHO Group 1 with right-heart catheterisation hemodynamics (mean pulmonary artery pressure, pulmonary vascular resistance, pulmonary capillary wedge pressure), vasoreactivity status, and current WHO functional class; the patient's documented current background PAH regimen with dates and dose; the rationale for adding an activin-pathway inhibitor (continuing symptoms despite combination background therapy, intermediate or high risk on standard risk-stratification scores, or recurrent clinical-worsening events); the proposed dosing plan starting at 0.3 mg/kg subcutaneous every three weeks with planned escalation to the 0.7 mg/kg target maintenance dose if tolerated; the pre-dose monitoring plan for hemoglobin and platelet count with label-defined thresholds for dose interruption, reduction, or discontinuation; and the prescribing physician's NMC registration number. The dispensing facility's drug licence, the chain-of-custody plan from the US specialty pharmacy to the Indian PAH centre, and the patient identifier complete the file.

The treating PAH specialist retains the clinical decision and the Pharmacovigilance Programme of India (PvPI) adverse-event reporting obligation through the Indian Pharmacopoeia Commission. Reserve Meds includes the PvPI reference in the physician documentation kit; the reporting obligation itself stays with the prescribing physician.

Common questions about Winrevair in India

Will Star Health, HDFC ERGO, ICICI Lombard, Apollo Munich, or Niva Bupa cover Winrevair?

Each plan handles named-patient imports case by case. None of the major Indian private insurers reimburse a Rule 36 personal import of an unregistered specialty biologic as a standard line item. Some plans have considered reimbursement on a case basis where the patient meets PAH-specialist criteria and the import route is a documented stocking workaround. Reserve Meds provides the itemised documentation that lets the insurer evaluate. Cash-pay is the operating default.

Will my CGHS or ESIC entitlement cover Winrevair?

CGHS provides for life-saving and anti-cancer medicines that are not in the standard formulary to be considered by an Expert Committee under Special DG (DGHS), case by case. Drugs not approved by the DCGI for use in India face a stricter Expert Committee review. ESIC's formulary is narrower. Neither scheme is structured for routine personal-import reimbursement of an activin-pathway inhibitor for PAH. Check eligibility with your CGHS Wellness Centre before assuming coverage.

What is the safety profile we should be aware of?

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. Hemoglobin and platelet counts are assessed before each dose, with label-defined thresholds for dose interruption or modification.

Can the patient self-administer at home in India?

After training by a healthcare professional on reconstitution and subcutaneous injection technique, eligible patients or caregivers may self-administer. The first doses are typically given under clinical supervision at the PAH centre. Reserve Meds confirms training capacity at the dispensing institution as part of intake; cold-chain integrity from the patient's refrigerator to the injection site is part of the patient-education kit.

Is there a competitor or alternative?

Winrevair is the only approved drug in its mechanistic class (activin signaling inhibition) for PAH. Other PAH therapies (endothelin receptor antagonists, PDE-5 inhibitors, guanylate cyclase stimulators, prostacyclin-pathway agents) operate via different mechanisms and are typically continued as background therapy alongside Winrevair rather than replaced by it. The choice to add Winrevair is a treating-clinician decision made on patient-specific factors. Reserve Meds does not make therapeutic substitution recommendations.

What is the typical course duration?

Treatment is chronic and indefinite as long as the patient benefits and tolerates therapy. There is no defined finite course. Reserve Meds plans repeat-shipment cadence at case acceptance to align with the every-three-week dosing schedule.

Where Reserve Meds fits in Winrevair cases

Reserve Meds is a US-based concierge coordinator. We do not replace your PAH specialist, do not replace CDSCO or the DCGI, and do not replace the dispensing PAH centre or the licensed specialty importer. What we do is orchestrate the US-side specialty pharmacy sourcing through Accredo or CVS Specialty under DSCSA serialization with full pedigree, validated 2 to 8 degree Celsius cold-chain logistics with temperature monitoring through to handoff, and the documentation kit your PAH specialist needs for the Form 12A filing. No prior Reserve Meds case experience exists for Winrevair in India as of this review, so standard NPP coordination applies with particular attention to cold-chain integrity across multi-leg

international transit, destination-centre training capacity for subcutaneous self-administration, and CBC monitoring discipline before each dose. A single named coordinator carries the case from intake through the every-three-week dose cycle.

Next step

If an Indian adult with WHO Group 1 PAH on background combination therapy has a PAH specialist considering add-on Winrevair, add the case to the waitlist. We will respond within 24 to 48 hours with a documentation kit for your specialist and an indicative cost range.

Reserved for you.
