

PRODUCT PROFILE

WINREVAIR Sotatercept-csrk, for injection, for subcutaneous use

Manufacturer

Merck Sharp & Dohme LLC

Indication

Sotatercept is indicated for the treatment of adults with pulmonary arterial hypertension (PAH; WHO [World Health Organization] Group 1) to increase exercise capacity, improve WHO functional class (FC) and reduce the risk of clinical worsening events.¹

Dosing and Administration

- Sotatercept is administered subcutaneously every 3 weeks based on patient body weight, starting at 0.3 mg/kg. After confirming acceptable hemoglobin and platelet counts, increase to 0.7 mg/kg every 3 weeks unless dosage adjustments are needed; do not initiate treatment if platelet count is less than 50,000/mm³.¹

Storage and Handling

- Store vials refrigerated at 2 C to 8 C (36 F to 46 F) in their original carton and do not freeze; the kit should remain refrigerated until use but can be kept at up to 25 C (77 F) for up to 24 hours.¹

Safety/Warnings

- Sotatercept may increase hemoglobin. Severe erythrocytosis may increase the risk of thromboembolic events or hyperviscosity syndrome.¹
- Sotatercept may decrease platelet count. Severe thrombocytopenia may increase the risk of bleeding.¹
- Serious bleeding (e.g., gastrointestinal, intracranial hemorrhage) was reported in 4% of patients taking sotatercept and 1% of patients taking placebo.¹
- Animal studies indicate that sotatercept may cause fetal harm during pregnancy and impair both female and male fertility.¹
- The most commonly reported adverse reactions (occurring in ≥ 10% of sotatercept-treated patients and at least 5% more than placebo) were headache (24.5%), epistaxis (22.1%), rash (20.2%), telangiectasia (16.6%), diarrhea (15.3%), dizziness (14.7%) and erythema (13.5%).¹

Disease State Background

PAH is a rare, progressive condition in which the small arteries in the lungs become thickened and narrowed, obstructing blood flow and causing increased lung blood pressure. It leads to high morbidity and a shortened lifespan.² The American Heart Association recommends early diagnosis to begin supportive treatment to reduce morbidity and to avoid shortened lifespans.³ Although PAH has been linked to genetic and environmental factors in some cases the majority of cases (approximately 50% to 60%) remain idiopathic, with no discernable underlying cause.^{4,5,6,7} An estimated 500 to 1000 cases are diagnosed in the United States each year.⁸ PAH, more common in women aged 30 to 60 years, disproportionately affects Black and Hispanic women.⁸

Place in Therapy

Currently, no cure exists for PAH and many patients experience poor outcomes after experiencing an aggressive and progressive disease course.⁹ Historically available treatments delay progression but mainly address symptoms rather than treat the underlying pathophysiology and disease mechanism.⁷ Sotatercept is the first FDA-approved therapy with a mechanism of action directly targeting the underlying cause of PAH.¹⁰ In clinical trials, sotatercept was shown to significantly improve exercise capacity and other secondary outcome measures in addition to background PAH therapy compared with background PAH therapy alone.¹¹

Managed Care Considerations

Sotatercept represents a novel therapy class and expands options for patients.

The American College of Chest Physicians (CHEST) guidelines suggest that dual combination therapy is superior to monotherapy to improve 6-minute walk testing (6WMT) and to reduce mortality for treatment-naïve PAH patients with WHO Functional Class II and III.¹² Mortality rates for patients with PAH remain high, with 3-year mortality rates reaching up to 55% for high-risk groups.

Despite lower mortality rates among patients treated with combination therapy compared with monotherapy (7% vs 13%, respectively), no difference was observed in a study between groups after 2 and 3 years.¹³

Market Insights

- Patients with PAH have faced limited treatment options and poor outcomes. Sotatercept, the first FDA-approved activin signaling inhibitor, improves the 6WMT and reduces mortality, offering a potential new standard of care as either add-on or first-line therapy. It targets the underlying cause of PAH, potentially reversing disease pathology and improving quality of life.
- Phase 3 trials show significant benefits, including improved exercise capacity at 24 weeks. Prior to sotatercept, no therapies targeted the abnormal pulmonary vasculature driving PAH.¹¹

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