WINREVAIR™
(sotatercept-csrk) for injection 45 mg, 60 mg

WHAT TO EXPECT WHEN ADDING *WINREVAIR* TO YOUR PATIENTS' PAH TREATMENT REGIMEN

STEP 1 Understand dosage and administration

STEP 2 Enrolling your patient into The Merck Access Program

STEP 3 Patient receives WINREVAIR

Indication

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

Selected Safety Information

Erythrocytosis: WINREVAIR may cause increases in hemoglobin (Hgb). Severe erythrocytosis may increase the risk of thromboembolic events or hyperviscosity syndrome. In clinical studies, moderate elevations in Hgb (>2 g/dL above upper limit of normal [ULN]) occurred in 15% of patients taking WINREVAIR while no elevations ≥4 g/dL above ULN were observed. Monitor Hgb before each dose for the first 5 doses, or longer if values are unstable, and periodically thereafter, to determine if dose adjustments are required.

Before prescribing WINREVAIR, please read the accompanying Prescribing Information. The Patient Information and Instructions for Use (1-vial kit, 2-vial kit) also are available.

Steps to initiate your patient on WINREVAIR

WINREVAIR™ (sotatercept-csrk) for injection 45 mg, 60 mg

STEP 1 Understand dosage and administration

☐ **Prior to starting WINREVAIR, review Section 2 (Dosage and Administration) of the Prescribing Information.**

Some key points to remember:

- WINREVAIR is administered once every 3 weeks by subcutaneous injection, according to patient body weight.
- The **recommended starting dose** of WINREVAIR is 0.3 mg/kg. Injection volume (mL) for starting dose is calculated based on patient weight as [(Weight (kg) x 0.3 mg/kg) ÷ 50 mg/mL].* See Section 2.1 of the Prescribing Information for details on selecting the appropriate kit type by injection volume.
  - **Obtain hemoglobin (Hgb) and platelet count prior to the first dose of WINREVAIR.**
  - **Do not initiate treatment if platelet count is <50,000/mm^3 (<50x10^9/L).**
- After verifying acceptable Hgb and platelet count, increase to the **recommended target dose** of 0.7 mg/kg. Injection volume (mL) for target dose is calculated based on patient weight as [(Weight (kg) x 0.7 mg/kg) ÷ 50 mg/mL].* See Section 2.2 of the Prescribing Information for details on selecting the appropriate kit type by injection volume.
- Continue treatment at 0.7 mg/kg every 3 weeks unless dosage adjustments are required.
- **Assess the need for dosage modifications due to increased Hgb or decreased platelet count. Check Hgb and platelet count before each dose for the first 5 doses, or longer if values are unstable. Thereafter, monitor Hgb and platelet count periodically. See Section 2.3 of the Prescribing Information for additional information about dose modifications.**

*Injection volume should be rounded to the nearest 0.1 mL for both starting and target doses.

Selected Safety Information *(continued)*

Severe Thrombocytopenia: WINREVAIR may decrease platelet count. Severe thrombocytopenia may increase the risk of bleeding. In clinical studies, severe thrombocytopenia (platelet count <50,000/mm^3 [<50 x 10^9/L]) occurred in 3% of patients taking WINREVAIR. Thrombocytopenia occurred more frequently in patients also receiving prostacyclin infusion. Do not initiate treatment if platelet count is <50,000/mm^3. Monitor platelets before each dose for the first 5 doses, or longer if values are unstable, and periodically thereafter to determine whether dose adjustments are required.

Ensure the patient is aware of The Merck Access Program (MAP). Contact your Merck Access and Reimbursement Manager (ARM) with any questions about The Merck Access Program Enrollment & Prescription Form for WINREVAIR.

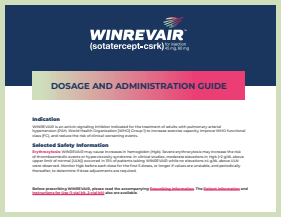
STEP 1

Understand dosage and administration *(continued)*

WINREVAIR™ (sotatercept-csrk) for injection 45 mg, 60 mg

- Administration is subject to monitoring of hemoglobin and platelet count.
- WINREVAIR is intended for use under the guidance of a healthcare professional. Patients and caregivers may administer WINREVAIR when considered appropriate and when they receive training and follow-up from the healthcare provider (HCP) on how to reconstitute, prepare, measure, and inject WINREVAIR.
- Confirm at subsequent visits that the patient and/or caregiver can correctly prepare and administer WINREVAIR, particularly if the dose changes or the patient requires a different kit.
- Refer to the Prescribing Information and Instructions for Use (IFU) for information on the proper preparation and administration of WINREVAIR.

Additional dosage and administration resources that can be provided by your Merck Rare Disease Account Specialist



Dosage and Administration Guide

Demonstration Kit

Selected Safety Information *(continued)*

Serious Bleeding: In clinical studies, serious bleeding (eg, gastrointestinal, intracranial hemorrhage) was reported in 4% of patients taking WINREVAIR and 1% of patients taking placebo. Patients with serious bleeding were more likely to be on prostacyclin background therapy and/or antithrombotic agents, or have low platelet counts. Advise patients about signs and symptoms of blood loss. Evaluate and treat bleeding accordingly. Do not administer WINREVAIR if the patient is experiencing serious bleeding.

Embryo-Fetal Toxicity: Based on findings in animal reproduction studies, WINREVAIR may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use an effective method of contraception during treatment with WINREVAIR and for at least 4 months after the final dose. Pregnancy testing is recommended for females of reproductive potential before starting WINREVAIR treatment.

STEP 2

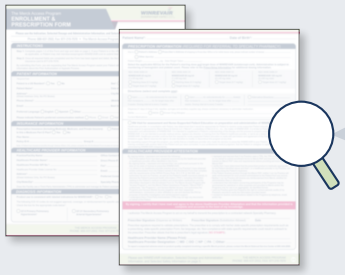
Enrolling your patient into The Merck Access Program*

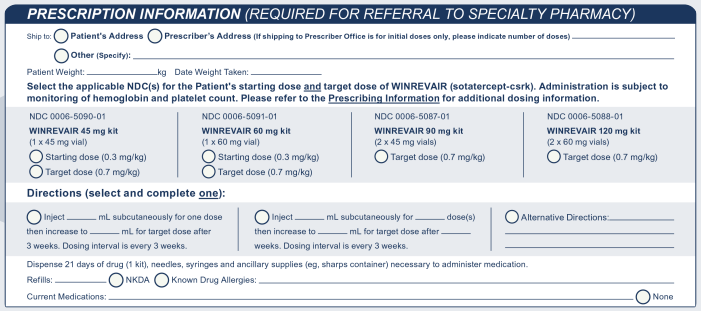
WINREVAIR™ (sotatercept-csrk) for injection 45 mg, 60 mg

Complete, sign and submit The Merck Access Program Enrollment & Prescription Form for WINREVAIR.

- Your patient can receive support from a Merck Access Program Patient Navigator if this form is submitted directly to The Merck Access Program.
- Visit The Merck Access Program healthcare provider (HCP) website and download, print, and fax the form to 877-219-7579.

WINREVAIR Merck Access Program Enrollment & Prescription Form





PRESCRIPTION INFORMATION *(REQUIRED FOR REFERRAL TO SPECIALTY PHARMACY)*

Ship to: ◯ **Patient's Address** ◯ **Prescriber's Address** (If shipping to Prescriber Office is for initial doses only, please indicate number of doses) _____

◯ **Other (Specify):** _____

Patient Weight: _____kg Date Weight Taken: _____

Select the applicable NDC(s) for the Patient's starting dose and target dose of WINREVAIR (sotatercept-csrk). Administration is subject to monitoring of hemoglobin and platelet count. Please refer to the Prescribing Information for additional dosing information.

NDC 0006-5090-01	NDC 0006-5091-01	NDC 0006-5087-01	NDC 0006-5088-01
WINREVAIR 45 mg kit (1 x 45 mg vial)	**WINREVAIR 60 mg kit** (1 x 60 mg vial)	**WINREVAIR 90 mg kit** (2 x 45 mg vials)	**WINREVAIR 120 mg kit** (2 x 60 mg vials)
◯ Starting dose (0.3 mg/kg)	◯ Starting dose (0.3 mg/kg)	◯ Target dose (0.7 mg/kg)	◯ Target dose (0.7 mg/kg)
◯ Target dose (0.7 mg/kg)	◯ Target dose (0.7 mg/kg)		

Directions (select and complete one):

◯ Inject _____ mL subcutaneously for one dose then increase to _____ mL for target dose after 3 weeks. Dosing interval is every 3 weeks.

◯ Inject _____ mL subcutaneously for _____ dose(s) then increase to _____ mL for target dose after _____ weeks. Dosing interval is every 3 weeks.

◯ Alternative Directions: _____

Dispense 21 days of drug (1 kit), needles, syringes and ancillary supplies (eg, sharps container) necessary to administer medication.

Refills: _____ ◯ NKDA ◯ Known Drug Allergies: _____

Current Medications: _____ ◯ None

Image depicts one section of a multipage form.

A patient must complete the Patient Authorization section of the Enrollment & Prescription Form to complete enrollment and receive support from The Merck Access Program. This can be done in one of two ways:

- Collect a patient's signature on page 4 of the form in the office, **OR**
- Advise your patient to visit The Merck Access Program patient website and provide an electronic signature.

If you and your patient enroll in The Merck Access Program, The Merck Access Program will send the prescription to the Specialty Pharmacy.

The Merck Access Program may be able to provide information about patient insurance coverage and out-of-pocket costs for WINREVAIR, co-pay assistance for eligible, commercially-insured patients, and how patients may access WINREVAIR. You can find more information on the access support provided through the program on page 6.

Selected Safety Information *(continued)*

Impaired Fertility: Based on findings in animals, WINREVAIR may impair female and male fertility. Advise patients on the potential effects on fertility.

To understand the full list of resources available to you and your patient, please visit WWW.MERCKACCESSPROGRAM-WINREVAIR.COM

***Enrollment into The Merck Access Program is not required. If you and your patient choose to enroll, The Merck Access Program may be able to help answer questions about access and support for eligible patients. If not, you may submit the prescription for WINREVAIR directly to the preferred in-network Specialty Pharmacy, including by using the prescription portion of the Enrollment & Prescription Form for WINREVAIR.**

STEP 3

Patient receives WINREVAIR

WINREVAIR™ (sotatercept-csrk) for injection 45 mg, 60 mg

- ☐ **Once the prescription is received, the Specialty Pharmacy will call the patient to schedule delivery.**
- ☐ **A pharmacist from the Specialty Pharmacy may contact your patient prior to shipping WINREVAIR. Remind patients to save the preferred Specialty Pharmacy contact information and accept all calls from the Specialty Pharmacy.**
- ☐ **The Specialty Pharmacy may contact you for additional clinical information in order to continue coordinating ongoing shipments.**

Merck Specialty Pharmacy Network Contact Information†

Accredo Health Group, Inc.
Phone: 866-344-4874
accredo.com

CVS Specialty Pharmacy
Phone: 877-242-2738
cvsspecialty.com

†Merck is not affiliated with and does not endorse one Specialty Pharmacy over another.

Remind patients to save the preferred Specialty Pharmacy contact information and to accept all calls from the Specialty Pharmacy. The Specialty Pharmacy will not ship the patient's medication without speaking to the patient first.

Selected Safety Information *(continued)*

Adverse Reactions: The most common adverse reactions occurring in the Phase 3 clinical trial (≥10% for WINREVAIR and at least 5% more than placebo) were as follows: headache (24.5% vs 17.5%), epistaxis (22.1% vs 1.9%), rash (20.2% vs 8.1%), telangiectasia (16.6% vs 4.4%), diarrhea (15.3% vs 10.0%), dizziness (14.7% vs 6.2%), and erythema (13.5% vs 3.1%).

Lactation: Because of the potential for serious adverse reactions in the breastfed child, advise patients that breastfeeding is not recommended during treatment with WINREVAIR, and for 4 months after the last dose.

Pediatric Use: The safety and effectiveness of WINREVAIR have not been established in patients less than 18 years of age.

Geriatric Use: A total of 81 patients ≥65 years of age participated in clinical studies for PAH, of which 52 (16%) were treated with WINREVAIR. Bleeding events occurred more commonly in the older WINREVAIR subgroup, but with no imbalance between age subgroups for any specific bleeding event.

Introducing The Merck Access Program

WINREVAIR™ (sotatercept-csrk) for injection 45 mg, 60 mg

A representative from The Merck Access Program may be able to:

- Identify and provide a summary of your patient's insurance benefits, including information about your patient's out-of-pocket costs.
- Provide information on co-pay assistance options, including the WINREVAIR co-pay coupon for eligible, privately insured patients.
- Communicate status updates to your patient regarding their coverage and access for WINREVAIR.
- Send a prescription to a Merck in-network Specialty Pharmacy based on your patient's insurance plan and preference.
- Refer your patients to the Merck Patient Assistance Program for eligibility determination (provided through the Merck Patient Assistance Program, Inc.).

How to contact The Merck Access Program

CALL
888-637-2502
[MONDAY- FRIDAY, 8:00 AM TO 8:00 PM ET]

FAX
877-219-7579
(TO SUBMIT ENROLLMENT & PRESCRIPTION FORM)

VISIT
WWW.MERCKACCESSPROGRAM-WINREVAIR.COM

You can access and download support resources at WWW.MERCKACCESSPROGRAM-WINREVAIR.COM

- Enrollment & Prescription Forms
- Example Enrollment & Prescription Form
- Prior Authorization Checklist
- Example Letter of Medical Necessity
- Guide to Appeals and Medical Exceptions
- Example Appeal Letter
- Independent Foundation Support Flashcard

Before prescribing WINREVAIR, please read the accompanying Prescribing Information. The Patient Information and Instructions for Use (1-vial kit, 2-vial kit) also are available.

MERCK