The Merck Access Program

ENROLLMENT & PRESCRIPTION FORM

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

Please see the Indication, Selected Dosage and Administration Information, and Selected Safety Information for WINREVAIR on page 6.

Phone: 888-637-2502, Fax: 877-219-7579 • The Merck Access Program, PO BOX 592188, Orlando, FL 32859

INSTRUCTIONS

Step 1: Complete pages 1-2 of this Form and sign and date on page 2. If your Patient is in the office, please ask your Patient to read and sign pages 3-5 or the Patient may visit WINREVAIRPatientAccess.iAssist.com to submit their consent electronically.

Step 2: Once all required fields are completed and the Form has been signed and dated, fax the document with a copy of the Patient's prescription insurance card to 877-219-7579. Please include all pages when submitting the completed Form.

By submitting this Form, you are requesting that The Merck Access Program assist your Patient with initiating a Benefits Investigation and/or obtaining information about the Prior Authorization or Appeals Process.

PATIENT INFORMATION

*Required Field

Patient is a US Resident*: ◯ Yes ◯ No Sex*: ◯ M ◯ F

Patient Name*: _____ Date of Birth*: _____

Address*: _____ City/State/Zip*: _____
(Street Address Only, No PO Boxes)

Phone (Home)*: _____ (Mobile): _____

Email: _____ Best time to contact: _____

Preferred Language: ◯ English ◯ Spanish ◯ Other: _____ Preferred Communication Method: ◯ Phone ◯ Email ◯ Mail

PRESCRIPTION INSURANCE INFORMATION

Please include Medicaid, Medicare, and Private Insurers. ◯ Patient Has No Insurance

Is this a Medicare Part D Plan? ◯ Yes ◯ No Plan Name: _____

Policy ID #: _____ Group #: _____ BIN #: _____ PCN #: _____

HEALTHCARE PROVIDER INFORMATION

Practice/Facility Name: _____ Office Contact Name*: _____

Healthcare Provider Name*: _____ Direct Phone #*: _____ Extension: _____

Healthcare Provider NPI No.*: _____ Fax*: _____

Healthcare Provider State License No.: _____ Email: _____

Address*: _____ Preferred Communication: ◯ Phone ◯ Fax ◯ Email
(Street Address Only, No PO Boxes)

City/State/Zip*: _____ Specialty Pharmacy Preference: ◯ Accredo Health Group, Inc. ◯ CVS Specialty Pharmacy

CLINICAL INFORMATION

Product use is consistent with labeled indications for WINREVAIR*: ◯ Yes ◯ No

Is patient currently taking WINREVAIR? ◯ Yes ◯ No Last injection date: _____

The following ICD-10 codes do not suggest approval, coverage, or reimbursement for specific uses or indications.

Check the box for the appropriate code below*:

ICD-10 I27.0 Primary Pulmonary Hypertension[1]

◯ Idiopathic PAH

◯ Heritable PAH

ICD-10 I27.21 Secondary Pulmonary Arterial Hypertension[1]

◯ Connective Tissue Disease

◯ Congenital Heart Disease

◯ Drugs/Toxins Induced

◯ Other

◯ Other: _____

_____

_____

Patient Name*: _____ **Date of Birth*:** _____

PRESCRIPTION INFORMATION (REQUIRED FOR REFERRAL TO SPECIALTY PHARMACY)

Please check the applicable box if prescription was already sent to the Specialty Pharmacy: ◯ Accredo Health Group, Inc. ◯ CVS Specialty Pharmacy

Ship to: ◯ Patient's Address ◯ Other (Specify): _____

Patient Weight: _____ kg Date Weight Taken: _____ Prescriber note to Specialty Pharmacy: _____

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. To learn about the recommended injection volume based on your patient's weight, see page 6 below, and visit merckconnect.com/winrevair/dosage.

Starting dose 0.3 mg/kg (select one below)

◯ NDC 0006-5090-01 **WINREVAIR 45 mg kit** (1 x 45 mg vial)	◯ NDC 0006-5091-01 **WINREVAIR 60 mg kit** (1 x 60 mg vial)

Target dose 0.7 mg/kg (select one below)

◯ NDC 0006-5090-01 **WINREVAIR 45 mg kit** (1 x 45 mg vial)	◯ NDC 0006-5091-01 **WINREVAIR 60 mg kit** (1 x 60 mg vial)	◯ NDC 0006-5087-01 **WINREVAIR 90 mg kit** (2 x 45 mg vials)	◯ NDC 0006-5088-01 **WINREVAIR 120 mg kit** (2 x 60 mg vials)

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

SUPPLEMENTAL NURSE-SUPPORTED EDUCATION

◯ **RN Visit for assessment and Nurse-Supported Patient Education on preparation and administration of WINREVAIR requested.**

Healthcare provider, in consultation with the Patient, has determined that it would be appropriate for the Patient to receive Nurse-Supported Patient Education at therapy initiation. Nurse support is sponsored by Merck Sharp & Dohme LLC ("Merck"), a subsidiary of Merck & Co., Inc., the maker of WINREVAIR. It is limited to Patient education about the preparation and administration of WINREVAIR. It is intended to supplement a Patient's understanding of the therapy and the process to properly prepare and administer WINREVAIR. It is not intended to provide medical advice, replace any direction or training from the Patient's healthcare provider, or serve as a reason to prescribe WINREVAIR. Healthcare provider confirms that this request for Nurse-Supported Patient Education is made with permission and agreement of the Patient. Program rules and limitations apply. Merck reserves the right in its sole discretion to modify or discontinue this program at any time.

By requesting support through this program, you certify that as a healthcare provider who made the decision to prescribe WINREVAIR to your Patient, you have provided training consistent with product label to the Patient and you have concluded, in your professional medical judgment, that the Patient or caregiver is capable of preparing and administering WINREVAIR independently.

HEALTHCARE PROVIDER ATTESTATION

I represent and warrant that I or others in my practice ("my Practice") have obtained written authorization from the patient listed above (the "Patient") that complies with the HIPAA Privacy Rule, and authorizes me, my Practice, and the Patient's health insurance plan(s), to disclose the Patient's protected health information ("PHI") to The Merck Access Program and the Merck Patient Assistance Program (together, "the Programs"), Merck Sharp & Dohme LLC, and each of their employees, affiliates, representatives, agents, contractors, and data processors, including the administrators of the Programs (collectively, "Merck"), and authorizes Merck to use and disclose the PHI for purposes of the Programs, including to provide benefits investigation and reimbursement support, and for Merck's related internal business purposes. If my Practice uses a Third-Party Administrator (TPA), I represent and warrant that the TPA is authorized to submit enrollment forms to Merck on my behalf, has been trained on the Merck Programs' rules and requirements, and will not sign any documents on behalf of the Patient.

I represent and warrant that I am authorized under the laws of my state of license to prescribe WINREVAIR, that I have determined that WINREVAIR is medically appropriate for the Patient, and that I will supervise the Patient's treatment. I certify that the Program Product is being used in an outpatient setting only. If the Patient receives WINREVAIR through the Merck PAP, neither I nor my Practice will receive any reimbursement from Merck, whether for administration fees or otherwise, from any source. I understand that any donated product from Merck PAP must be returned if the specific eligible patient is unable to receive treatment for any reason and may not be used for any other patient other than the Merck PAP patient for whom it was intended. I and my Practice grant the Programs the right to conduct periodic audits of my Practice's records to verify the information provided herein.

I consent to receive communications related to the Programs by telephone, email, and/or fax.

By signing, I certify that I have read and agree to the above Healthcare Provider Attestation and that the information provided is complete and accurate to the best of my knowledge.

I authorize The Merck Access Program to act on my behalf to transmit the prescription to a contracted network Specialty Pharmacy.

Prescriber Signature (Dispense as Written)	**Prescriber Signature** (Substitution Allowed)	**Date***

Prescriber signature required to validate prescriptions. The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription Form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to the prescriber. Prescriber attests that this is prescriber's legal signature (**NO STAMPS**).

Healthcare Provider Name (Please Print): _____

Healthcare Provider Designation: ◯ **MD** ◯ **DO** ◯ **NP** ◯ **PA** ◯ **Other:** _____

To report a suspected adverse event or product quality complaint involving a specific Merck product, please contact the Merck National Service Center at 800-444-2080.

Patient Name*: _____ **Date of Birth*:** _____

PROGRAM ENROLLMENT & CONSENT TO PROCESS HEALTH INFORMATION

The Merck Access Program may provide information and support related to your insurance benefits for WINREVAIR™ (sotatercept-csrk), estimated out-of-pocket costs, and co-pay assistance options for which you may be eligible. The Merck Access Program will use your data only for the purposes listed below. Patient or Legal Representative signature is required for participation in The Merck Access Program.

If I am eligible to participate, then by consenting below, I agree to enroll in The Merck Access Program, sponsored by Merck Sharp & Dohme LLC. By choosing to enroll, I agree that The Merck Access Program and the Merck Patient Assistance Program (the "Programs"), Merck Sharp & Dohme LLC, and each of their employees, affiliates, representatives, agents, contractors, and data processors, including the administrators of the Programs (collectively, "Merck"), may collect, use, and disclose health information about me, including the details I provided on this form, information about my participation in the Programs, and other health information about me, such as my diagnosis and medication, to facilitate my participation in the Programs, including, as applicable, to: (i) verify my eligibility to enroll in the Programs and enroll me in the Programs for which I am eligible; (ii) coordinate my benefits and access to my Merck medication, provide reimbursement support, and administer the Programs; (iii) ensure compliance with laws and the rules of the Programs; and (iv) facilitate related internal business purposes, such as to provide customer support and evaluate and improve the Programs. I also agree that Merck may contact me via telephone, email, or mail using the contact information I provided on this form for purposes related to the Programs.

I understand that I am not required to consent to this processing of my health information. However, if I do not consent, I will not be able to participate in the Programs, as the processing of my health information is necessary for Merck to facilitate my participation in the Programs.

If I consent, I have the right to withdraw my consent at any time by calling 888-637-2502, by mailing The Merck Access Program, PO Box 592188, Orlando, FL 32859, or via web at WINREVAIRPatientAccess.iAssist.com. For more information about Merck's privacy practices and for privacy disclosures applicable to residents of certain US states, see our US Supplemental Privacy Notice at msdprivacy.com/us/en/supp-notice/ and our Consumer Health Data Privacy Policy at msdprivacy.com/us/en/chd-policy/.

◯ **I CONSENT** to the terms above and agree to enroll into The Merck Access Program.

◯ **I DO NOT CONSENT** to the terms above.

PATIENT AUTHORIZATION FOR DISCLOSURE OF HEALTH INFORMATION

By signing below, I authorize each of my physicians, pharmacies, and health plans to obtain, use, and disclose my protected health information, including the details I provided on this form, information about my participation in The Merck Access Program, the Merck Patient Assistance Program, and the WINREVAIR Patient Support Program (collectively, the "Programs"), and other health information about me, such as my diagnosis, symptoms, medication, and inferences derived from the same (collectively, "PHI"), to The Merck Access Program, the Merck Patient Assistance Program, Merck Sharp & Dohme LLC, and each of their employees, affiliates, representatives, agents, contractors, and data processors, including the administrators of the Programs (collectively, "Merck"), to facilitate my participation in the Programs, including for the itemized purposes listed below. I also agree that Merck may obtain, use, and disclose my PHI to my physicians, pharmacies, and health plans, to my Legal Representative (if any), as well as to Merck vendors and third parties as appropriate to facilitate my participation in the Programs, including, as applicable, to: (i) verify my eligibility to enroll in the Programs and enroll me in the Programs for which I am eligible; (ii) coordinate my benefits and access to my Merck medication, provide reimbursement support, and administer the Programs; (iii) ensure compliance with laws and the rules of the Programs; and (iv) facilitate related internal business purposes, such as to provide customer support and evaluate and improve the Programs.

Continued on Next Page

Patient Name*: _____ Date of Birth*: _____

PATIENT AUTHORIZATION FOR DISCLOSURE OF HEALTH INFORMATION (CONTINUED)

By signing this authorization, I also acknowledge my understanding that:

- The PHI disclosed pursuant to this authorization, once disclosed, may no longer be governed by certain federal or state privacy laws and may be subject to re-disclosure. However, I also understand that unless I separately consent to additional uses/disclosures, Merck intends to use and disclose my PHI only for the purposes described in this authorization.
- My specialty pharmacies may receive compensation in connection with disclosure of my PHI to Merck as described in this authorization.
- If I choose not to provide this authorization, that decision will not affect my eligibility for, or receipt of, treatment, including Merck products, or healthcare insurance benefits. However, I understand that I will not be able to receive any assistance from the Programs for which I may be eligible.
- I may cancel this authorization at any time by calling 888-637-2502, mailing a written request to The Merck Access Program, PO Box 592188, Orlando, FL 32859, or via web at WINREVAIRPatientAccess.iAssist.com. I understand that canceling my authorization will mean that my physicians, pharmacies, and health plans, as well as Merck, may no longer rely on this authorization to disclose my PHI, but that any use or disclosure of such information that occurs before my cancellation is received will be unaffected by my cancellation.
- If I do not cancel this authorization, the authorization will expire 5 years from the date of signature (or the maximum period allowed by applicable state law, if less than 5 years). The administrators of the Programs will retain the information they have collected about me in accordance with Merck's records retention policy.
- I understand that I am entitled to a copy of my signed authorization and that I can obtain copies by downloading them after submission online or by calling 888-637-2502.

By signing, I certify that I have read and agree to the above Patient Authorization for Disclosure of Health Information.

SIGNATURE OF PATIENT OR LEGAL REPRESENTATIVE: _____ **Date*:** _____

A Legal Representative is a person who has legal authority under applicable state law to bind you (the Patient) by signing each authorization or declaration in the Enrollment Form.

Name of Signing Party (Please Print): _____

DECLARATION OF LEGAL REPRESENTATIVE

◯ I declare that I am the Legal Representative of the Patient and that I have the legal authority under applicable state law to bind the Patient by signing each authorization or declaration in this Enrollment Form.

Phone Number of Legal Representative: _____ **Relationship of Legal Representative to the Patient:** _____

Patient Name*: _____ **Date of Birth*:** _____

OPTIONAL ENROLLMENT IN WINREVAIR™ (sotatercept-csrk) PATIENT SUPPORT PROGRAM

If I am eligible to participate, then by consenting below, I also request to be enrolled into the WINREVAIR Patient Support Program that will provide me educational resources, product information, and other communications specific to WINREVAIR.

By choosing to enroll, I agree that Merck Sharp & Dohme LLC, and each of its employees, affiliates, representatives, agents, contractors, and data processors, including the administrators of the WINREVAIR Patient Support Program (collectively, "Merck"), may collect, use, and disclose health information about me, including the details I provided on this form, information about my participation in the Programs, and other health information about me, such as my diagnosis, symptoms, medication, and inferences derived from the same, to facilitate my participation in the WINREVAIR Patient Support Program, and specifically, to: (i) verify my eligibility to enroll in the WINREVAIR Patient Support Program and enroll me, if eligible; (ii) send me information, resources, and communications about WINREVAIR that are part of the WINREVAIR Patient Support Program; and (iii) facilitate related internal business purposes for the WINREVAIR Patient Support Program, such as to provide customer support and evaluate and improve the program.

I understand that I am not required to consent to this processing of my health information. However, if I do not consent, I will not be able to participate in the WINREVAIR Patient Support Program, as the processing of my health information is necessary for Merck to facilitate my participation in the WINREVAIR Patient Support Program. My decision to enroll or not enroll in the WINREVAIR Patient Support Program will not impact my eligibility for The Merck Access Program, Merck Patient Assistance Program, or receipt of treatment, including Merck products, or healthcare insurance benefits.

If I consent, I have the right to withdraw my consent at any time by calling 888-637-2502, by mailing The Merck Access Program, PO Box 592188, Orlando, FL 32859, or via web at WINREVAIRPatientAccess.iAssist.com. For more information about Merck's privacy practices and for privacy disclosures applicable to residents of certain US states, see our US Supplemental Privacy Notice at msdprivacy.com/us/en/supp-notice/ and our Consumer Health Data Privacy Policy at msdprivacy.com/us/en/chd-policy/.

◯ **I CONSENT** to the collection of my health information per the terms above.

◯ **I CONSENT** to the sharing and disclosure of my health information as identified above.

◯ **I DO NOT CONSENT** to the terms above.

**Please note: You must check both boxes starting with "I Consent" above to enroll in the WINREVAIR Patient Support Program. Participation is voluntary, and if you do not wish to enroll, please check "I DO NOT CONSENT to the terms above."*

OPTIONAL MOBILE AUTHORIZATION

I agree that The Merck Access Program, the Merck Patient Assistance Program, the WINREVAIR Patient Support Program (collectively, the "Programs"), Merck Sharp & Dohme LLC, and each of their employees, affiliates, representatives, agents, contractors, and data processors, including the administrators of the Programs (collectively, "Merck"), to the extent I voluntarily enroll in the Programs by Merck, may send me communications about resources and services related to my enrollment in the Programs via telephone call and text message. The number and type of calls and text messages will be based upon my program selections, and message and data rates may apply. At any time, I may request to stop telephone calls or text messages by following the opt-out directions provided during those communications. I UNDERSTAND THAT THESE COMMUNICATIONS MAY USE PRERECORDED/ARTIFICIAL VOICE MESSAGES AND/OR AN AUTOMATED SYSTEM AND THAT I DO NOT NEED TO AGREE TO RECEIVE CALLS/TEXT MESSAGES AS A CONDITION OF PURCHASING OR RECEIVING ANY PRODUCTS OR SERVICES FROM MERCK.

◯ **I CONSENT** to the terms above. Please list your mobile phone number: _____

◯ **I DO NOT CONSENT** to the terms above.

OPTIONAL MARKETING AND BUSINESS CONSENT FOR COLLECTION OF HEALTH INFORMATION (EXCEPT MD RESIDENTS)

If I consent below, I agree that The Merck Access Program and Merck Sharp & Dohme LLC, and each of their employees, affiliates, representatives, agents, contractors, and data processors, including the administrators of The Merck Access Program (collectively, "Merck"), may (1) collect and process; and (2) if I also agree, share and disclose, health information about me, including the details I provided on this form, information about my participation in The Merck Access Program, and other health information, such as:

- Individual health conditions, treatment, diseases, or diagnosis;
- Use or purchase of prescribed medication;
- Diagnoses or diagnostic testing, treatment, or medication;
- Data that identifies a consumer seeking healthcare services; and
- Inferences regarding a consumer's health derived from non-health information.

(collectively, "Health Information") for marketing purposes related to other Merck products and services, as well as for market research and related business purposes not necessary for my enrollment in The Merck Access Program.

I understand that I am not required to consent, and that I can participate in The Merck Access Program even if I do not consent to collection of my health information for such purposes.

If I consent, I have the right to withdraw my consent at any time by calling 888-637-2502 or via web at WINREVAIRPatientAccess.iAssist.com.

◯ **I CONSENT** to the optional collection of my health information per the terms above.

◯ **I CONSENT** to the optional sharing and disclosure of my health information as identified above by The Merck Access Program, sponsored by Merck Sharp & Dohme LLC.

◯ **I DO NOT CONSENT** to the terms above.

**Please note: You must check both boxes starting with "I Consent" above to opt-in to marketing and other business use of health information. Participation is voluntary, and if you do not wish to enroll, please check "I DO NOT CONSENT to the terms above."*

INDICATION

WINREVAIR™ (sotatercept-csrk) is an activin signaling inhibitor indicated for the treatment of adults with pulmonary arterial hypertension (PAH, Group 1 pulmonary hypertension) to improve exercise capacity and World Health Organization (WHO) functional class (FC), and reduce the risk of clinical worsening events including hospitalization for PAH, lung transplantation and death.

SELECTED DOSAGE AND ADMINISTRATION INFORMATION

Recommended Starting Dosage: WINREVAIR is administered once every 3 weeks by subcutaneous injection according to patient body weight. The starting dose of WINREVAIR is 0.3 mg/kg. 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).

Injection volume for starting dose is calculated based on patient weight as follows:

$$\textit{Injection Volume (mL)} = \frac{\textit{Weight (kg)} \times 0.3\ \textit{mg/kg}}{50\ \textit{mg/mL}}$$

Injection volume should be rounded to the nearest 0.1 mL.

For example: (70 kg x 0.3 mg/kg) ÷ 50 mg/mL = 0.42 mL, rounds to 0.4 mL.

See Table 1 for selecting the appropriate kit based on calculated injection volume for starting dose.

Table 1: Kit Type Based on Injection Volume for Dose of 0.3 mg/kg

Injection Volume (mL)	Kit Type
0.2 to 0.9	45 mg kit (containing 1 x 45 mg vial)
1 to 1.1	60 mg kit (containing 1 x 60 mg vial)

Recommended Target Dosage: After verifying acceptable Hgb and platelet count, increase to the target dose of 0.7 mg/kg. Continue treatment at 0.7 mg/kg every 3 weeks unless dosage adjustments are required.

Injection volume for target dose is calculated based on patient weight as follows:

$$\textit{Injection Volume (mL)} = \frac{\textit{Weight (kg)} \times 0.7\ \textit{mg/kg}}{50\ \textit{mg/mL}}$$

Injection volume should be rounded to the nearest 0.1 mL.

For example: (70 kg x 0.7 mg/kg) ÷ 50 mg/mL = 0.98 mL, rounds to 1 mL.

See Table 2 for selecting the appropriate kit based on calculated injection volume for target dose.

Table 2: Kit Type Based on Injection Volume for Dose of 0.7 mg/kg

Injection Volume (mL)	Kit Type
0.4 to 0.9	45 mg kit (containing 1 x 45 mg vial)
1 to 1.2	60 mg kit (containing 1 x 60 mg vial)
1.3 to 1.8	90 mg kit (containing 2 x 45 mg vials)
1.9 to 2.4	120 mg kit (containing 2 x 60 mg vials)

Preparation and Administration: 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 Prescribing Information and Instructions for Use (IFU) for detailed instructions on the proper preparation and administration of WINREVAIR.

SELECTED SAFETY INFORMATION

Erythrocytosis: WINREVAIR may increase hemoglobin (Hgb). Severe erythrocytosis may increase the risk of thromboembolic events or hyperviscosity syndrome. 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.

Severe Thrombocytopenia: WINREVAIR may decrease platelet count. Severe thrombocytopenia may increase the risk of bleeding. 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.

Serious Bleeding: In clinical studies, serious bleeding (e.g., gastrointestinal, intracranial hemorrhage) was reported in 4% vs 1% (STELLAR) and 7% vs 5% (ZENITH) of patients taking WINREVAIR vs placebo, respectively. 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. Do not administer WINREVAIR if the patient is experiencing serious bleeding.

Embryo-Fetal Toxicity: 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.

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

Adverse Reactions: The most common adverse reactions (≥10% for WINREVAIR and at least 5% more than placebo) occurring in the STELLAR phase 3 clinical trial were 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 6.3%), and erythema (13.5% vs 3.1%). The most common adverse reactions in the ZENITH trial were infections (67.4% vs 44.2%), epistaxis (45.3% vs 9.3%), diarrhea (25.6 % vs 17.4%), telangiectasia (25.6 % vs 3.5%), increased hemoglobin (15.1% vs 1.2%), rash (10.5% vs 4.7%), erythema (10.5% vs 3.5%), and gingival bleeding (10.5% vs 2.3%).

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 final dose.

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.

Reference: 1. CMS. ICD-10-CM Tabular List of Disease and Injuries. https://www.cms.gov/files/zip/2025-code-tables-tabular-and-index.zip. January 10, 2025.

MERCK

THE MERCK ACCESS PROGRAM
PHONE: 888-637-2502, FAX: 877-219-7579