

PATIENT INFORMATION
WINREVAIR™ (WIN-reh-vair)
(sotatercept-csrk)
for injection, for subcutaneous use

What is WINREVAIR?

WINREVAIR is a prescription medicine used to treat adults with pulmonary arterial hypertension (PAH). PAH is a type of high blood pressure in the arteries of your lungs.

WINREVAIR can:

- improve your ability to exercise and perform normal activities with fewer symptoms, and
- reduce the risk of your physical condition and symptoms worsening, including lowering your risk of hospitalization for PAH, lung transplant, and death.

It is not known if WINREVAIR is safe and effective in children under 18 years of age.

What should I tell my healthcare provider before taking WINREVAIR?

- Tell your healthcare provider about:
 - **All of your medical conditions**
 - **All of the medicines you take, including** prescriptions and over-the-counter medicines, vitamins, or herbal supplements

If you are able to get pregnant:

- WINREVAIR may harm your unborn baby. Tell your healthcare provider if you are pregnant or planning to get pregnant.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with WINREVAIR.
- Your healthcare provider should do a pregnancy test before you start taking WINREVAIR.
- You should use effective birth control during treatment with WINREVAIR and for at least 4 months after your final dose. Ask your healthcare provider about birth control methods that may be right for you.
- You or your healthcare provider should report any exposure to WINREVAIR during pregnancy by calling 1-877-888-4231.

If you are breastfeeding or planning to breastfeed:

- Tell your healthcare provider if you are breastfeeding or planning to breastfeed. It is not known if WINREVAIR passes into breast milk.
- Do not breastfeed during treatment with WINREVAIR and for 4 months after your final dose. Talk to your healthcare provider about the best way to feed your baby.
- You or your healthcare provider should report any exposure to WINREVAIR during breastfeeding by calling 1-877-888-4231.

Before you take WINREVAIR:

- If your healthcare provider decides that you or a caregiver can give your injections of WINREVAIR at home, you or your caregiver should receive training from your healthcare provider on the right way to prepare and inject WINREVAIR. Do not try to inject WINREVAIR until you have been shown how to inject WINREVAIR by your healthcare provider.
- Your healthcare provider will do a blood test before your first 5 doses of WINREVAIR, longer if needed, and then from time to time to check your levels of hemoglobin (a protein in red blood cells that carries oxygen) and platelets (blood cells that help blood clot). After each of these blood tests, your healthcare provider may delay treatment or change your dose if needed.
- **See the detailed “Instructions for Use” booklet that comes with WINREVAIR for information on how to prepare and inject a dose of WINREVAIR.**

How should I take WINREVAIR?

- Use WINREVAIR exactly as your healthcare provider tells you to.
- You will give WINREVAIR every 3 weeks as an injection just under your skin (subcutaneous) in your:
 - **stomach** (abdomen) at least 2 inches away from the belly button, **or**
 - **upper thigh**

- You should inject WINREVAIR right away after mixing the medicine powder with the sterile water for injection, but no later than 4 hours after mixing.

Your prescribed dose:

- Your healthcare provider will tell you how much WINREVAIR to inject and when to inject it. This is because your prescribed dose depends on your body weight and blood tests.
- Do not change your dose or stop taking WINREVAIR without talking to your healthcare provider.
- Do not take WINREVAIR more often than your healthcare provider tells you to. If you are not sure when to take WINREVAIR, call your healthcare provider.
- Your healthcare provider may delay treatment, change your dose, or stop treatment depending on how you respond to WINREVAIR.

What if I take the wrong dose or miss my dose?

- If you give more than or less than your prescribed dose, call your healthcare provider right away.
- If you miss your dose of WINREVAIR:
 - If it has been 3 days or fewer, give it as soon as possible. You can then follow your usual schedule for your next dose.
 - If it has been more than 3 days, call your healthcare provider for what to do.

What are the possible side effects of WINREVAIR?

WINREVAIR may cause serious side effects including:

- **High level of hemoglobin in your blood.** High levels of hemoglobin are common with WINREVAIR and can be severe and increase your risk for blood clots. Your healthcare provider will do blood tests to check your hemoglobin levels before starting and regularly during treatment with WINREVAIR.
- **Severely low number of platelets in your blood.** Low platelet counts are common with WINREVAIR and can be severe and increase your risk of bleeding. Your healthcare provider will do blood tests to check your platelet levels before starting and regularly during treatment with WINREVAIR. Tell your healthcare provider if you develop easy bruising or bleeding, bleeding that does not stop, or nosebleeds.
- **Serious bleeding.** You are more likely to have serious bleeding if you have low platelet counts, take prostacyclin medicines to treat PAH, or take medicines to help keep blood clots from forming. Tell your healthcare provider if you develop any signs or symptoms of bleeding, including:
 - vomiting blood or your vomit looks like coffee-grounds
 - pink or brown urine
 - red or black stools that look like tar
 - coughing up blood or blood clots
 - persistent headaches
 - nausea
 - dizziness or feeling weak
 - persistent abdominal cramps
 - severe back pain
 - abnormally heavy menstrual bleeding
- **Decreased fertility.** WINREVAIR may affect female and male fertility, which may affect your ability to have children. Talk to your healthcare provider if this is a concern for you.

The most common side effects of WINREVAIR include:

- | | |
|--|-----------------|
| • infections | • diarrhea |
| • headache | • dizziness |
| • nose bleeds | • redness |
| • rash | • bleeding gums |
| • tiny blood vessels that look like pink or red lines on the skin (spider veins) | |

These are not all the possible side effects of WINREVAIR.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store WINREVAIR?

- Store WINREVAIR in the refrigerator at 36°F to 46°F (2°C to 8°C). Do not freeze.
- Store in the original carton to protect from light.

Keep WINREVAIR and all medicines out of the reach of children and pets.

General information about the safe and effective use of WINREVAIR.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use WINREVAIR for a condition for which it was not prescribed. Do not give WINREVAIR to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about WINREVAIR that is written for healthcare professionals.

What are the ingredients in WINREVAIR?

Active ingredient: sotatercept-csrk

Inactive ingredient(s): citric acid monohydrate, polysorbate 80, sodium citrate, and sucrose.

Manufactured by: Merck Sharp & Dohme LLC, Rahway, NJ 07065, USA.

US License Number 0002

For patent information: www.msd.com/research/patent

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For more information, call 1-877-888-4231, or go to www.WINREVAIR.com.

This Patient Information has been approved by the U.S. Food and Drug Administration

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