

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

WINREVAIR®

Sotatercept for injection

Read this carefully before you start taking **WINREVAIR®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **WINREVAIR®**.

What is WINREVAIR® used for?

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

How does WINREVAIR® work?

WINREVAIR® is an activin receptor type IIA-Fc (ActRIIA-Fc) fusion protein which works to lower the blood pressure in your lungs.

What are the ingredients in WINREVAIR®?

Medicinal ingredient: sotatercept

Non-medicinal ingredients: citric acid monohydrate, polysorbate 80, sucrose, and tri-sodium citrate dihydrate at pH 5.8.

WINREVAIR® comes in the following dosage forms:

Solution for injection: 45 mg or 60 mg for subcutaneous use.

To help avoid side effects and ensure proper use, talk to your healthcare professional before WINREVAIR® is administered. Talk about any health conditions or problems you may have, including if you:

- Have or have had any medical conditions, and about any allergies.
- Are pregnant or if you are planning to get pregnant. **WINREVAIR®** may harm your unborn baby.
- Become pregnant or think you may be pregnant while taking **WINREVAIR®**.
- Are breastfeeding or plan to breastfeed. It is not known if **WINREVAIR®** passes into breast milk.

Pregnancy

- Your healthcare professional should do a pregnancy test before you start taking **WINREVAIR®**.
- You should use effective birth control when taking **WINREVAIR®**.
- You should continue using effective birth control for at least 4 months after your last dose if you stop taking **WINREVAIR®**. Ask your healthcare professional about birth control methods that would work well for you.
- You or your healthcare professional should report any exposure to **WINREVAIR®** during pregnancy by calling 1-800-567-2594.

Breast-feeding

- Do not breastfeed while taking WINREVAIR®.
- Do not breastfeed for at least 4 months after your last dose if you stop taking WINREVAIR®. Talk to your healthcare professional about the best way to feed your baby.

Fertility

- WINREVAIR® may decrease female and male fertility.

Children

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

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

It is unknown if WINREVAIR® interacts with other medicines or supplements.

How to take WINREVAIR® (kit):

Read the separate **Instructions For Use** booklet that comes with your kit.

- Take WINREVAIR® exactly as your healthcare professional tells you to.
- You will take WINREVAIR® every 3 weeks as an injection just under your skin (subcutaneous) only in these injection sites:
 - **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, but no later than 4 hours after mixing.

How will you receive WINREVAIR®? (vial)

- You will be given WINREVAIR® every 3 weeks as an injection just under your skin (subcutaneous) only in these injection sites:
 - **stomach** (abdomen) at least 2 inches away from the belly button
 - **upper thigh**
 - **upper arm**

Your dose:

- Your dose of WINREVAIR® depends on your body weight and blood tests.
- Your healthcare professional will tell you how much WINREVAIR® to take and when to take it.
- Do not change your dose or stop taking WINREVAIR® without talking to your healthcare professional.
- Do not take WINREVAIR® more often than your healthcare professional tells you to. If you are not sure when to take WINREVAIR®, call your healthcare professional.

Your healthcare professional will monitor your dose:

- Your healthcare professional 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.

- Before your first dose and regularly while taking WINREVAIR[®], your healthcare professional will do blood tests. These are done so that your healthcare professional can monitor you and find the best dose for you.
- Your healthcare professional may adjust your dose, delay treatment, or stop treatment depending on how you respond to WINREVAIR[®].

Overdose:

If you take too much WINREVAIR[®], call your healthcare professional.

If you think you, or a person you are caring for, have taken too much WINREVAIR[®], contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose (kit):

- If you miss your prescribed dose of WINREVAIR[®], take it within 3 days and follow your original schedule for your next dose. If not taken within 3 days, call your healthcare professional for guidance.

Missed Dose (vial):

- If you miss your appointment to be given WINREVAIR[®], call your healthcare professional immediately to reschedule your appointment.

What are possible side effects from using WINREVAIR[®]?

These are not all the possible side effects you may have when taking WINREVAIR[®]. If you experience any side effects not listed here, tell your healthcare professional.

The most common side effects of WINREVAIR[®] are:

- nose bleeds (epistaxis)
- telangiectasia (also called spider veins or tiny blood vessels that look like pink or red lines on the skin)
- headache
- diarrhea

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Serious bleeding: persistent headache, nausea, weakness, black or tarry stool, blood in your stool, bright red blood from vomiting or coughing, persistent abdominal cramps, severe back pain, or abnormally heavy menstrual bleeding, more likely to happen if you take WINREVAIR with certain medicines. Your healthcare professional will inform you on how to recognize them.		√	
RARE			
Erythrocytosis: high level of hemoglobin (a protein in red blood cells that carries oxygen): This can raise the chance of a blood clot forming that can block a blood vessel.		√ Your healthcare professional will do blood tests to check your hemoglobin levels before starting and regularly during treatment with WINREVAIR®.	
Severe Thrombocytopenia: low number of platelets (blood cells that help blood clot): easy bruising, continued bleeding from cuts, and nosebleeds.		√ Your healthcare professional will do blood tests to check your platelet level before starting and regularly during treatment with WINREVAIR®.	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store WINREVAIR® in the refrigerator at 2°C to 8°C. Do not freeze.
- Store in the original container to help protect from light.
- Contact your healthcare professional if the unused injection kit has been out of the refrigerator for an extended period of time.
- After you mix the medicine powder with the sterile water (provided in the kit), it is recommended that you inject it right away, but no later than 4 hours after mixing.

Keep out of reach and sight of children.

If you want more information about WINREVAIR®:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html> or the manufacturer's website www.merck.ca, or by calling 1-800-567-2594.

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