

GET SUPPORT FOR OPSUMIT® (macitentan)

Once you and your healthcare provider have decided OPSUMIT® is right for you, Janssen CarePath will help you find the resources you may need to get started and stay on track.

Janssen
CarePath

Opsumit
macitentan tablets 10 mg

What is OPSUMIT®?

OPSUMIT® is a prescription medicine used to treat pulmonary arterial hypertension (PAH, WHO Group 1). PAH is high blood pressure in the arteries of your lungs. OPSUMIT® can:

- Improve your ability to exercise as measured by the 6-minute walk distance (6MWD). In a clinical study of mainly WHO FC II-III patients, those taking OPSUMIT® walked, on average, 22 meters farther at Month 6 than patients not taking it
- Improve some of your symptoms
- Help slow down the progression of your disease
- Lower your chance of being hospitalized for PAH

It is not known if OPSUMIT® is safe and effective in children.

The most important information about OPSUMIT®

Do not take OPSUMIT® if you are pregnant or trying to get pregnant. OPSUMIT® can cause serious birth defects if taken while pregnant. While taking OPSUMIT®, and for 1 month after stopping OPSUMIT®, women who are able to get pregnant must use 2 acceptable forms of birth control. Women who have had a tubal sterilization, a progesterone implant, or have an IUD (intrauterine device) do not need a second form of birth control. Talk to your doctor or gynecologist about which birth control to use while on OPSUMIT®.

Please see additional Important Safety Information on reverse side of this brochure. Also, see accompanying full Prescribing Information and Medication Guide, including an Important Warning about Serious Birth Defects, in the back pocket of this brochure.

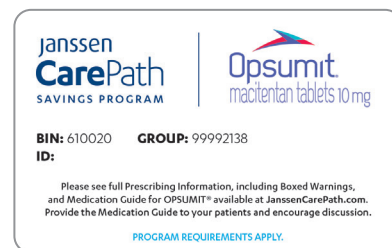
FC=functional class; WHO=World Health Organization.

PAYING FOR OPSUMIT® (macitentan)



At Janssen, we don't want cost to get in the way of treatment you need. We can help you explore options to lower your out-of-pocket cost for OPSUMIT®. No matter what type of insurance you have—or even if you don't have insurance—Janssen CarePath can help explain your medication insurance coverage and potential out-of-pocket costs and help find programs that may help you pay for OPSUMIT®.

Janssen CarePath Oral PAH Savings Program for OPSUMIT®



If you use commercial or private health insurance to pay for your medication:

Eligible patients using commercial insurance can save on out-of-pocket medication costs for OPSUMIT®. Eligible patients **pay \$5 per prescription fill** with a \$20,000 maximum program benefit per calendar year across all oral PAH therapies in the program. Not valid for patients using Medicare, Medicaid, or other government-funded programs to pay for their medications. Terms expire at the end of each calendar year and may change. There is no income requirement. See full eligibility requirements at [OPSUMIT.JanssenCarePathSavings.com](https://www.OPSUMIT.JanssenCarePathSavings.com).

If you use a government-funded healthcare program to pay for OPSUMIT® or have no insurance coverage and need help paying for your medication:

Janssen CarePath can provide information about other resources that may be able to help with your out-of-pocket medication costs for OPSUMIT®.

Call a Janssen CarePath Care Coordinator at **866-228-3546** or visit [JanssenCarePath.com](https://www.JanssenCarePath.com) for more information about affordability programs and independent foundations* that may have funding available.

*Independent co-pay assistance foundations have their own rules for eligibility. We cannot guarantee a foundation will help you. We only can refer you to a foundation that supports your disease state. This information is provided as a resource for you. We do not endorse any particular foundation.

OPSUMIT® (macitentan) VOUCHER PROGRAM

A free 30-day trial offer is available for eligible patients to help you become familiar with OPSUMIT®.

At the conclusion of the program, you and your healthcare provider decide if it is appropriate to continue treatment. Subject to 1 (one) use per lifetime for the first 30-day supply of OPSUMIT®. Terms expire at the end of each calendar year and may change. This Voucher Program is open to patients who have commercial insurance, government coverage, or no insurance coverage; however, there is no guarantee of continuous accessibility after the program ends. Ask your doctor about the OPSUMIT® Voucher Program.

By using the OPSUMIT® Voucher Program, you confirm that you have read, understood, and agree to the program requirements shown below and at [JanssenCarePath.com/Opsumit-Voucher](https://www.JanssenCarePath.com/Opsumit-Voucher).

OPSUMIT® Voucher Program Terms and Conditions

- You may be eligible for the OPSUMIT® Voucher Program if you have been prescribed OPSUMIT® and are 18 years of age or older
- Patients enrolled in a Medicare Part D plan may be eligible for this free 30-day trial offer, but may not submit a claim for the costs paid by this program to count toward true out-of-pocket (TrOOP) costs
- Out-of-pocket costs paid by this program may not be submitted as a claim for payment to any third-party payer, pharmaceutical patient assistance foundation, or account such as a Flexible Spending Account (FSA), a Health Savings Account (HSA), or a Health Reimbursement Account (HRA)
- Subject to 1 (one) use per lifetime for the first 30-day supply of OPSUMIT®
- Terms expire at the end of each calendar year. Program subject to change or discontinuation without notice, including in specific states
- It is important that you understand that the personal information provided may also be used to learn more about the people who use OPSUMIT®, and to improve the information we provide to people who are being treated with OPSUMIT®. Actelion Pharmaceuticals US, Inc., will not share your information with anyone else except as required by law
- This program offer may not be combined with any other coupon, discount, prescription savings card, free trial, or other offer. The selling, purchasing, trading, or counterfeiting of this card is prohibited. Offer good only in the United States and the Commonwealth of Puerto Rico. Void where prohibited, taxed, or otherwise restricted by law

Janssen CarePath is in no way an extension of medical treatment provided by healthcare professionals to individual patients. You may discontinue your participation at any time by calling 866-228-3546, Monday-Friday, 8:00 AM to 8:00 PM ET.

PAH COMPANION PROGRAM

PAH Companions provide one-on-one educational support to help patients start and stay on their prescribed Janssen medication, provide patient resources to partner with their healthcare team, and help them better manage their pulmonary arterial hypertension (PAH).* As part of the program, PAH Companions are ready to answer patients' questions. Patients who have enrolled can talk to a PAH Companion by calling 866-300-1818, Monday-Friday, 8:00 AM to 8:00 PM ET.

*The PAH Companion Program is limited to education about your Janssen therapy, its administration, and/or PAH. It is intended to supplement your understanding of your therapy, and does not provide medical advice or replace a treatment plan from your doctor, nurse, or healthcare team.

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CONTACT JANSSEN CAREPATH



Visit [JanssenCarePath.com/Opsumit](https://www.JanssenCarePath.com/Opsumit)



Need Help? Call a Janssen CarePath Care Coordinator at 866-228-3546, Monday-Friday, 8:00 AM to 8:00 PM ET.

Multilingual phone support is available.

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Johnson & Johnson

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OPSUMIT® (macitentan) IMPORTANT SAFETY INFORMATION

The most important information about OPSUMIT®

Do not take OPSUMIT® if you are pregnant or trying to get pregnant. OPSUMIT® can cause serious birth defects if taken while pregnant.

Women who are able to get pregnant must have negative pregnancy tests:

- Before starting OPSUMIT®
- Each month while taking OPSUMIT®
- For 1 month after stopping OPSUMIT®

Your doctor will decide when you should take pregnancy tests.

You are medically able to get pregnant if you are a woman who fits all of the following guidelines:

- has started puberty, even if you have not had a menstrual period yet
- has a uterus
- has not gone through menopause (menopause means you have not had a menstrual period for at least 12 months for natural reasons, or have had your ovaries removed)

You are not medically able to get pregnant if you are a woman who fits at least 1 of the following guidelines:

- has not started puberty
- does not have a uterus
- has gone through menopause (you have not had a menstrual period for at least 12 months for natural reasons, or have had your ovaries removed)
- is infertile for other medical reasons and this infertility is permanent and cannot be reversed

While taking OPSUMIT®, and for 1 month after stopping OPSUMIT®, women who are able to get pregnant must use 2 acceptable forms of birth control. Women who have had a tubal sterilization, a progesterone implant, or have an IUD (intrauterine device) do not need a second form of birth control. Talk to your doctor or gynecologist about which birth control to use while on OPSUMIT®.

If you decide to change your form of birth control, talk with your doctor or gynecologist. This way you can be sure to choose another acceptable form of birth control. **Also review the Medication Guide for acceptable birth control options.**

It's important not to have unprotected sex while taking OPSUMIT®. Tell your doctor right away if you have unprotected sex, think your birth control has failed, miss a menstrual period, or think you may be pregnant. He or she may recommend using a form of emergency birth control.

If you are the parent or caregiver of a female child who started taking OPSUMIT® before reaching puberty, check with your child regularly for any signs of puberty. **Your child may reach puberty before having her first menstrual period.** Talk to your doctor if you think your child is showing signs of puberty or if you have any questions about the signs of puberty.

Before starting OPSUMIT®, women must enroll in a program called the OPSUMIT® Risk Evaluation and Mitigation Strategy (REMS). If you are a woman who is able to get pregnant, you must talk to your doctor to learn the benefits and risks of OPSUMIT®. You must also agree to all of the instructions in the program. Men who are prescribed OPSUMIT® do not need to enroll in this program.

Who should not take OPSUMIT®?

Do not take OPSUMIT® if you are pregnant, plan to become pregnant, or become pregnant during treatment with OPSUMIT®. OPSUMIT® can cause serious birth defects. See "The most important information about OPSUMIT®."

Do not take OPSUMIT® if you are allergic to macitentan or any of the ingredients in OPSUMIT®. See the Medication Guide for a complete list of ingredients in OPSUMIT®.

Talk to your doctor about all your medical conditions, as well as all the medicines, vitamins, and supplements you take. OPSUMIT® and other medicines may affect each other causing side effects. Tell your doctor right away if you take an HIV medicine. Do not start any new medicine until you check with your doctor.

What should I avoid while taking OPSUMIT®?

- **Do not get pregnant.** OPSUMIT® can cause serious birth defects. See "The most important information about OPSUMIT®." If you miss a menstrual period or think you may be pregnant, call your doctor right away
- **You should not breastfeed if you take OPSUMIT®.** It is not known if OPSUMIT® passes into your breast milk. Talk to your doctor about the best way to feed your baby

What are the possible side effects of OPSUMIT®?

OPSUMIT® can cause serious side effects, including:

- **Serious birth defects.** See "The most important information about OPSUMIT®"
- **Some medicines that are like OPSUMIT® can cause liver problems.** Your doctor should do blood tests to check your liver before you start OPSUMIT®. Tell your doctor if you have any of these symptoms, which could be a sign of liver problems while on OPSUMIT®:
 - Nausea or vomiting
 - Pain in the upper right stomach
 - Feeling tired
 - Loss of appetite
 - Your skin or the whites of your eyes turn yellow
 - Dark urine
 - Fever
 - Itching
- **Fluid retention** could happen during the first weeks after starting OPSUMIT®. Tell your doctor right away if you notice unusual weight gain or swelling in your ankles or legs. Your doctor will look for the cause
- **Low red blood cell levels (anemia) can happen while taking OPSUMIT®, usually during the first weeks after starting OPSUMIT®. In some cases a blood transfusion may be needed, but this is not common.** Your doctor will do blood tests to check for anemia before you start OPSUMIT®. You may also need to do these blood tests while taking OPSUMIT®

- **Decreased sperm counts.** OPSUMIT®, and other medicines like OPSUMIT®, may cause decreased sperm counts in men who take these medicines. If fathering a child is important to you, tell your doctor

The most common side effects are:

- Stuffy nose or sore throat
- Irritation of the airways (bronchitis)
- Headache
- Flu
- Urinary tract infection

Talk to your doctor if you have a side effect that bothers you or does not go away. These are not all the possible side effects of OPSUMIT®. For more information, ask your doctor or pharmacist.

You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying full Prescribing Information and Medication Guide, including an Important Warning about Serious Birth Defects in the back pocket of this brochure.

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