



WHEN YOU'RE ABLE TO DO MORE,
YOUR WORLD CAN GET BIGGER.

OPSUMIT® Patient Guide

What is OPSUMIT® (macitentan)?

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.

Please see Important Safety Information throughout this brochure and on pages 24-26. Also, see accompanying full Prescribing Information and Medication Guide, including an Important Warning about Serious Birth Defects, in the back pocket of this brochure.

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®.



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DISCOVER WHAT'S POSSIBLE WITH OPSUMIT®
AS A PART OF YOUR TREATMENT PLAN.

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.**

Please see "The most important information about OPSUMIT®" continued on page 5.

2 Please see Important Safety Information throughout this brochure and on pages 24-26. Also, 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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PAH: A Closer Look

Pulmonary arterial hypertension (PAH, WHO Group 1) is a chronic disease involving high blood pressure in the arteries of your lungs. It's a progressive condition that gets worse over time, making it more difficult for blood to flow through your lungs. This can force your heart to work harder than normal and may limit your physical activities.¹⁻⁵

PAH diagnosis

PAH diagnosis can be challenging because symptoms are often similar to other conditions affecting the lungs and heart. Doctors start by ruling out other diseases and then perform tests to diagnose PAH.⁶

These tests may include:



▶ An **echocardiogram (Echo)** is a type of ultrasound that shows the size, shape, and function of your heart⁷



▶ A **lung scan** (also called a ventilation/perfusion or **V/Q scan**) is used to measure air and blood flow in your lungs⁸



▶ A **pulmonary function test (PFT)** is a breathing test that measures how well your lungs work⁸



▶ A **right heart catheterization (RHC)** is used to measure pressures in the heart and the arteries in your lungs⁸

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PAH treatments target 3 pathways^{1,3,5}

Blood vessels in your lungs may be affected when there is either too much or too little of certain naturally occurring substances in your body: endothelin, nitric oxide, and/or prostacyclin. There are PAH treatments available that target each of these pathways:

Endothelin pathway

Endothelin receptor antagonists (ERAs), such as OPSUMIT[®], work here.

Nitric oxide pathway

Phosphodiesterase type-5 inhibitors (PDE-5 inhibitors) and soluble guanylate cyclase stimulators (sGCs) work here.

Prostacyclin pathway

Prostacyclin, prostacyclin analogs, and prostacyclin receptor agonists work here.

The most important information about OPSUMIT[®] (continued)

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.


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6 Please see Important Safety Information throughout this brochure and on pages 24-26. Also, see accompanying full Prescribing Information and Medication Guide, including an Important Warning about Serious Birth Defects, in the back pocket of this brochure.

How OPSUMIT® Can Help

OPSUMIT® is an FDA-approved ERA shown to help slow down the progression of PAH (WHO Group 1). Disease progression included the need for injectable PAH medication or other worsening of PAH (decreased 6MWD, PAH symptoms getting worse, and the need for new PAH treatment).¹



OPSUMIT® can be a central part of treating PAH¹

OPSUMIT® can be taken alone or in combination with PDE-5 inhibitors or inhaled prostanoids, which are types of PAH medicines. Talk to your doctor about how OPSUMIT® can be part of your treatment plan.



Convenient dosing to fit your daily routine¹

- ▶ OPSUMIT® is a once-daily pill
- ▶ You can take it with or without food

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®” starting on page 3.

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.

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®.

What should I avoid while taking OPSUMIT®?

- **Do not get pregnant.** OPSUMIT® can cause serious birth defects. See “The most important information about OPSUMIT®” starting on page 3. 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

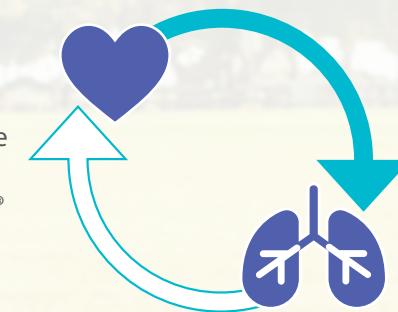
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How OPSUMIT® Can Help (continued)

OPSUMIT® helps open blood vessels between the heart and lungs⁹

When you have PAH, your body may produce too much of a substance called endothelin. This can cause the blood vessels in your lungs to narrow, restricting blood flow and putting strain on the heart. OPSUMIT® targets the endothelin pathway specifically, and works to open these narrow blood vessels.^{1,5,9}



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®" starting on page 3
- **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

Please see "What are the possible side effects of OPSUMIT®?" continued on page 11.

Please see Important Safety Information throughout this brochure and on pages 24-26. Also, 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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How OPSUMIT® Can Help (continued)

OPSUMIT® clinical trial^{1,2}



OPSUMIT® was studied in the largest long-term clinical trial of any ERA in PAH, which^{1,2,4}:

- ▶ Compared 242 patients taking OPSUMIT® with 250 patients not taking it
- ▶ Included patients from 39 countries who were treated with OPSUMIT® for an average of 2 years
- ▶ Included a majority of patients who were already being treated with a specific therapy for PAH, either PDE-5 inhibitors (61%) and/or inhaled prostanoids (6%)

What are the possible side effects of OPSUMIT®? (continued)

- **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.


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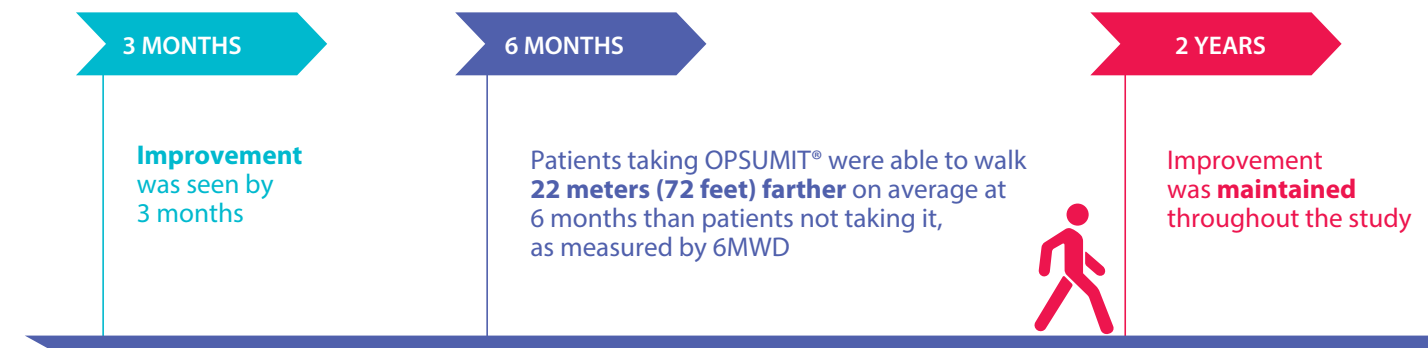
Please see Important Safety Information throughout this brochure and on pages 24-26. Also, see accompanying full Prescribing Information and Medication Guide, including an Important Warning about Serious Birth Defects, in the back pocket of this brochure.

How OPSUMIT® Can Help (continued)

OPSUMIT® clinical trial results^{1,2}

OPSUMIT® helped patients walk farther

6-minute walk distance (6MWD) measures the distance you can walk in 6 minutes. It is one test that your doctor may perform to assess your condition.



Improvement was measured by the 6MWD in a clinical trial that compared 242 patients taking OPSUMIT® with 250 patients not taking OPSUMIT®. Patients took OPSUMIT® for an average of 2 years. At the beginning of the trial, the majority of patients were being treated with a specific therapy for PAH, either PDE-5 inhibitors (61%) and/or inhaled prostanoids (6%).

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.

Please see "The most important information about OPSUMIT®" continued on page 14.


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How OPSUMIT® Can Help (continued)

OPSUMIT® clinical trial results^{1,10}

OPSUMIT® improved patients' ability to do more physical activity

More patients taking OPSUMIT® saw an improvement of at least one functional class. At Month 6 in the clinical trial, 22% of patients taking OPSUMIT® improved their functional class compared with 13% of patients not taking it.

Improved functional class can mean the ability to do more physical activity with:



Functional class is a common way for doctors to assess the seriousness of your PAH, which can help them with making treatment decisions. The higher the functional class, the more severe the disease. Improved functional class means you can do more physical activity with fewer limitations. It does not always mean symptom improvement. According to PAH experts, maintaining or improving functional class is often an important goal of PAH treatment. Talk to your doctor to discuss your own treatment goals.

The most important information about OPSUMIT® (continued)

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)

14 Please see "The most important information about OPSUMIT®" continued on page 16.



Please see Important Safety Information throughout this brochure and on pages 24-26. Also, 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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How OPSUMIT® Can Help (continued)

OPSUMIT® clinical trial results^{1,2}

OPSUMIT® reduced the risk of PAH progression

Patients taking OPSUMIT® were 45% less likely to have their PAH progress than patients not taking it.*

LESS RISK
that PAH will progress

MORE TIME
without a serious
PAH event

*In the clinical trial, disease progression included the need for injectable PAH medication or other worsening of PAH (decreased 6MWD, PAH symptoms getting worse, and the need for new PAH treatment). Overall, 31.4% of patients who took OPSUMIT® and 46.4% of patients who did not take OPSUMIT® had their PAH progress. On average, patients took OPSUMIT® for 2 years.

The most important information about OPSUMIT® (continued)

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

OPSUMIT® lowered the chance of being hospitalized due to PAH



Patients taking OPSUMIT® were
50% LESS LIKELY
TO BE HOSPITALIZED FOR PAH

In the clinical trial, 20.7% of patients who took OPSUMIT® and 33.6% of patients who did not take OPSUMIT® were hospitalized for PAH. On average, patients took OPSUMIT® for 2 years.

The most important information about OPSUMIT® (continued)

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.**

Please see “The most important information about OPSUMIT®” continued on page 18.

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Getting Started on OPSUMIT®

3 important steps to getting your medicine

Here's what you can expect before your prescription arrives:

1

Your doctor prescribes OPSUMIT®

- ▶ You and your doctor will review important information, including the OPSUMIT® Medication Guide, and complete the OPSUMIT® Prescription Statement of Medical Necessity (PSMN) form. You should also ask questions about OPSUMIT® at this time
- ▶ If you're a woman, you will need to enroll in the OPSUMIT® Risk Evaluation and Mitigation Strategy (REMS) Program, due to the **risk of serious birth defects**. You can learn more about this by speaking with your doctor and reading the Important Safety Information on pages 24-26 of this brochure
- ▶ If you're a woman who can get pregnant, you must have a negative pregnancy test before starting OPSUMIT®, each month while taking OPSUMIT®, and for 1 month after you stop taking OPSUMIT®. Your doctor will help you choose acceptable forms of birth control

The most important information about OPSUMIT® (continued)

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.

Please see "The most important information about OPSUMIT®" continued on page 20.



2



Your Janssen CarePath Care Coordinator contacts you

Expect a call from your Care Coordinator to:

- ▶ Review your health plan benefits to help answer questions you may have about insurance coverage
- ▶ Identify and coordinate with a specialty pharmacy to arrange shipment of your Janssen medication

3



Your specialty pharmacy calls you before OPSUMIT® ships

OPSUMIT® is not available at your local retail pharmacy and is only available through a specialty pharmacy, which will send your medicine to your home.

- ▶ Each month, your specialty pharmacy will call you to review your current medicines, discuss the OPSUMIT® Medication Guide, and reorder your OPSUMIT®. The specialty pharmacy may not ship your medicine if they don't speak with you first. Be sure to answer when they call and call them back if they leave a message
- ▶ Make sure you or your caregiver will be home to receive your package
- ▶ If you're a woman who is able to get pregnant, you need to use 2 acceptable forms of birth control and take pregnancy tests as recommended by your doctor. Do not get pregnant. Tell your doctor if you think you may be pregnant. Your specialty pharmacy will confirm that you've completed your monthly pregnancy test. Your refill may not be done on time if you have not had your pregnancy test

Please see Important Safety Information throughout this brochure and on pages 24-26. Also, 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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Getting Started on OPSUMIT® (continued)

Things to remember when taking your medicine

Take OPSUMIT® exactly how your doctor recommends. If you miss a dose, take it as soon as you remember that same day. You can take the next dose of OPSUMIT® at your regular time. Do not take 2 doses at the same time to make up for a missed dose.



Tell your doctor:

- ▶ If you take too much OPSUMIT®. Call your doctor or go to the nearest hospital emergency room right away
- ▶ If you have any side effect that bothers you or does not go away
- ▶ **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
- ▶ About any new medicines. Do not start any new medicine until you check with your doctor

DO NOT:

- ▶ Stop taking OPSUMIT® unless you're advised to do so by your doctor
- ▶ Split, crush, or chew OPSUMIT® tablets

What you may expect from OPSUMIT® treatment

It may take some time to feel the benefits of treatment. One of the first changes you may notice is the ability to do more physical activity with fewer symptoms (eg, chest pain, feeling tired, or being short of breath). If your symptoms do not get worse over time, it may mean that your PAH treatments are working. Talk to your healthcare team about any changes in your symptoms.

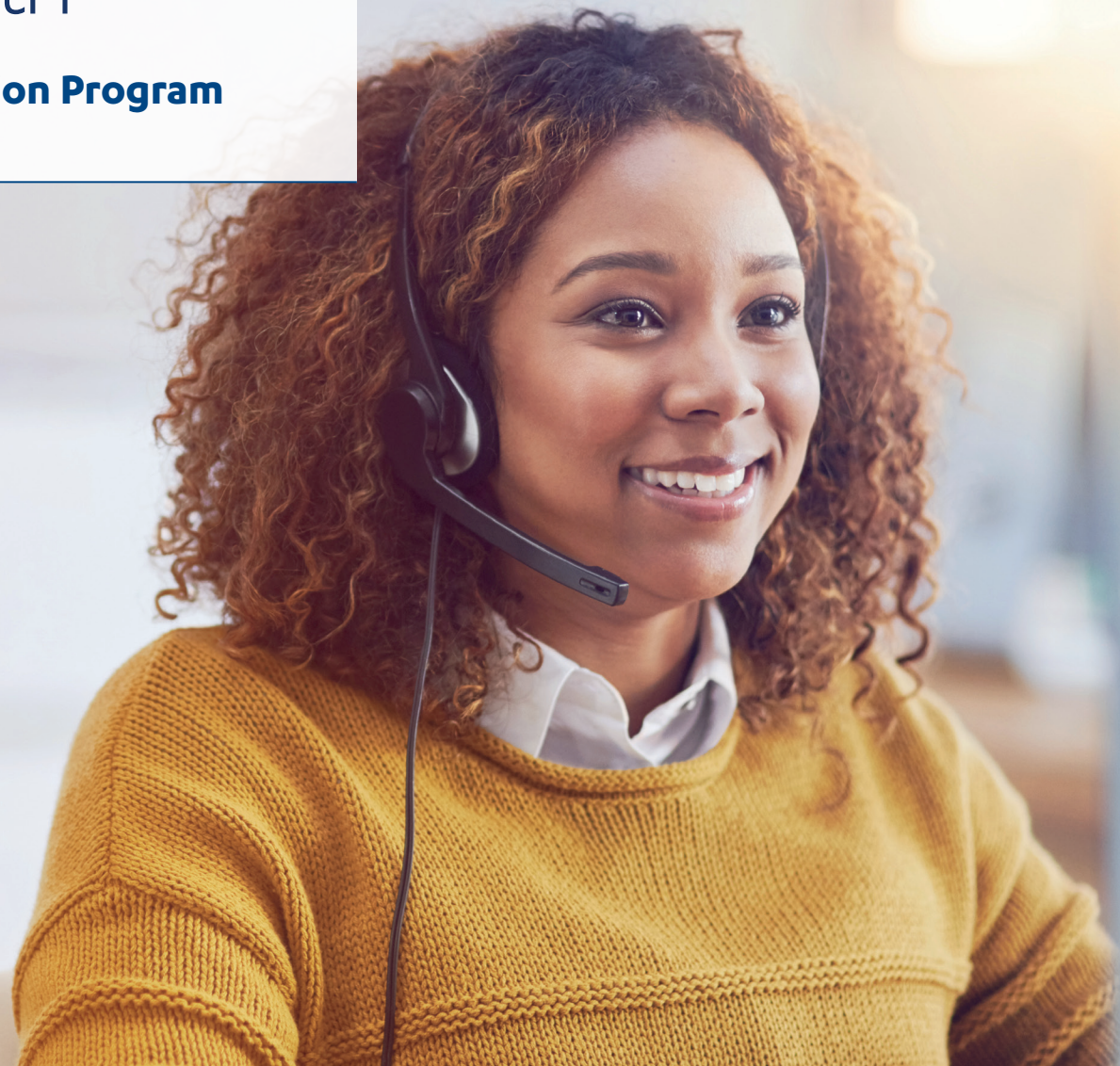
The most important information about OPSUMIT® (continued)

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.



Please see Important Safety Information throughout this brochure and on pages 24-26. Also, 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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We're Committed to People With PAH

With Janssen, you're never alone

Through Janssen CarePath, you'll get information about your condition and be better prepared to take a more active role in your treatment. Taking OPSUMIT® (macitentan) also means receiving support from different resources, including:

PAH Companion*—Connect directly with your dedicated PAH Companion* for one-on-one educational support

Janssen CarePath Care Coordinators who provide assistance with insurance and access to coverage as well as information about financial assistance options for eligible patients, if needed

Ongoing mailers about PAH education, tracking symptoms, healthy diet ideas, and tips on how to have better talks with your doctor

CONTACT A **PAH COMPANION***

PAH Companions* are ready to answer your questions. Patients who have enrolled can talk to a PAH Companion* by calling

866-300-1818

Mon-Fri, 8 AM-9 PM ET.

*PAH Companions provide one-on-one educational support to help you start and stay on your prescribed Janssen medication, provide resources to partner with your healthcare team, and help you better manage your pulmonary arterial hypertension (PAH).

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Important Safety Information

The most important information about OPSUMIT® (macitentan)



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

Continued on next page.

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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Important Safety Information (continued)

What are the possible side effects of OPSUMIT® (macitentan)?

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.

Notes

Have questions?



For information on paying for OPSUMIT®, call a Janssen CarePath Care Coordinator at

866-228-3546

Mon-Fri, 8 AM-8 PM ET



PAH Companions* are ready to answer your questions. Patients who have enrolled can talk to a PAH Companion* by calling

866-300-1818

Mon-Fri, 8 AM-9 PM ET



For more information anytime, visit

Opsumit.com

*The PAH Companion Program is limited to education for patients about their Janssen therapy, its administration, and/or their disease. It is intended to supplement a patient's understanding of their therapy, and is not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe.

Please see Important Safety Information throughout this brochure and on pages 24-26. Also, 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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