



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

Important Safety Information

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 taking a placebo (sugar pill)
- 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 18-20. Also, see accompanying full Prescribing Information and Medication Guide, including an Important Warning about Serious Birth Defects, for OPSUMIT[®], in the back pocket of this brochure.

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. Before starting OPSUMIT[®], during treatment, and for one month after stopping OPSUMIT[®], women who are able to get pregnant should use effective 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.

SUPPORT FOR EVERY STEP OF YOUR TREATMENT JOURNEY.



3 Important Steps That Should Have Already Occurred

You may be receiving this brochure because you and your healthcare team have decided that starting treatment with OPSUMIT® (macitentan) was right for you and your health. To guide you on your PAH journey, here's a step-by-step guide to help you stay on track.



STEP 1 | A Call from Your J&J withMe Care Coordinator

A J&J withMe Care Coordinator should have contacted you to discuss any insurance-related questions and work with you to get your medication from the pharmacy. If you did not receive a call, please call our J&J withMe Care Coordinators at **866-228-3546**, Monday-Friday, 8 AM-8 PM ET.



STEP 2 | A Call from Your Specialty Pharmacy

Your PAH medicine is only available through a Specialty Pharmacy and they will deliver your prescription to your home. Your Specialty Pharmacy should have contacted you to schedule your shipment. They should continue to call you every month to confirm your prescription order and schedule the following month's delivery. If you did not receive a call, please call your J&J withMe Care Coordinator at **866-228-3546**, Monday-Friday, 8 AM-8 PM ET.

NOTE: The Specialty Pharmacy may not ship your medicine without speaking to you first. If you miss a call from the Specialty Pharmacy, please be sure to call them back to confirm your medicine shipment and save the number to your phone so you recognize future calls.



STEP 3 | Medicine Delivery

You should have received your medication. If it has not been delivered, please call your J&J withMe Care Coordinator at **866-228-3546**, Monday-Friday, 8 AM-8 PM ET.



Data rates may apply.

Important Contact Information

Make sure that you scan the QR code using the camera on your smartphone and that your phone is connected to the internet. This will ensure that the contact information is added directly to your contacts and will also help you identify when your Care Team is calling you. If you don't have a smartphone, we encourage you to manually input and save the contact information above to your phone.

▶ You can also find steps to expect on **page 21** of this brochure

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You're Not Alone.



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For support on living with PAH, talk with a trained, dedicated PAH Companion. You can learn more about PAH Companion withMe by calling **866-300-1818** Mon-Fri, 8 AM-9 PM ET

Learn more at pahcompanion.com



For more information, visit opsumit.com

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PAH: A Closer Look

Pulmonary arterial hypertension (PAH, WHO Group 1) is high blood pressure in the arteries of your lungs. PAH is a chronic and progressive disease. This means that over time, PAH will get worse, and it may limit your physical activities.

What is OPSUMIT® (macitentan)?

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- 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 taking a placebo (sugar pill)
- Improve some of your symptoms
- Help slow down the progression of your disease
- Lower your chance of being hospitalized for PAH

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Important Safety Information about OPSUMIT® (macitentan)

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 should have a negative pregnancy test before starting OPSUMIT®. Your doctor will decide when you should take pregnancy tests.

You are 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 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

Before starting OPSUMIT®, during treatment, and for one month after stopping OPSUMIT®, women who are able to get pregnant should use effective 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.

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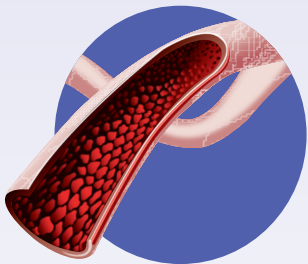
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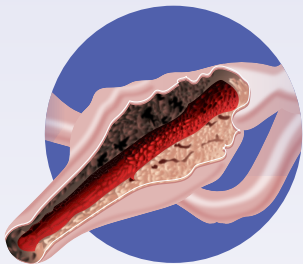


Three Pathways to Treat PAH

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: nitric oxide, endothelin, and/or prostacyclin. There are PAH treatments available that target each of the three pathways. OPSUMIT® (macitentan) targets the endothelin pathway specifically and works to open these narrow blood vessels.



Healthy Artery



PAH Progression

Nitric Oxide Pathway

The body may not have enough NITRIC OXIDE to keep arteries from getting stiff.

Phosphodiesterase type-5 inhibitors (PDE5is) and soluble guanylate cyclase stimulators (sGCs) target this pathway

OPSUMIT® (macitentan) works here

Endothelin Pathway

Too much ENDOTHELIN can cause blood vessels to narrow and tighten.

Endothelin receptor antagonists (ERAs), such as OPSUMIT®, target this pathway

Prostacyclin Pathway

The body may not make enough PROSTACYCLIN to keep arteries open.

Prostacyclin, prostacyclin analogs, and prostacyclin receptor agonists target this pathway

Important Safety Information (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.

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Important Safety Information (continued)

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.

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Getting Started on OPSUMIT® (macitentan)

Taking OPSUMIT®



Once-Daily Dose of OPSUMIT®:

- ▶ It is a once-daily pill that can be taken with or without food
- ▶ It can be taken alone or in combination with PDE5 inhibitors or inhaled prostanoids, which are types of PAH medicines



Instructions for taking OPSUMIT®:

- ▶ Take OPSUMIT® exactly as your doctor recommends
- ▶ Do not stop taking OPSUMIT® unless you're advised to do so by your doctor
- ▶ You can take OPSUMIT® with or without food
- ▶ If you miss a dose of OPSUMIT®, 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 about any of the following:

- ▶ If you take too much OPSUMIT®
- ▶ You have a side effect that bothers you or that won't go away
- ▶ Any new medicines you start taking
- ▶ 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.



Important Safety Information (continued) 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®."

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Important Safety Information (continued)

If you are a woman who is able to get pregnant, you should talk to your doctor to learn the benefits and risks of OPSUMIT®.

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How OPSUMIT® (macitentan) Can Help

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. 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.

OPSUMIT® clinical trial results



OPSUMIT® was studied in the largest long-term clinical trial of any endothelin receptor antagonist (ERA) in PAH:

- ▶ Compared 242 patients taking OPSUMIT® with 250 patients taking a placebo (sugar pill)
- ▶ 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 PDE5 inhibitors (61%) and/or inhaled prostanoids (6%)



Important Safety Information (continued)

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.

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Important Safety Information (continued)

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®.

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How OPSUMIT® (macitentan) Can Help (continued)

OPSUMIT® clinical trial results

OPSUMIT® lessens the chance that PAH will progress. In a clinical trial, patients taking OPSUMIT® (31.4%) were 45% less likely to have their PAH progress than patients taking a placebo (sugar pill) (46.4%). This means more time without a serious PAH event.

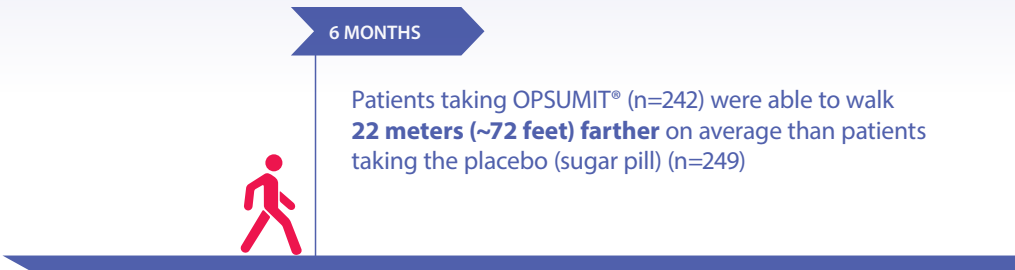
Less chance of PAH-related hospitalization. There was a 50% reduction in the risk of PAH-related hospitalization for patients taking OPSUMIT® (n=242) vs the placebo (sugar pill) (n=249). 18.6% of patients taking OPSUMIT® vs 31.6% of patients taking placebo (a sugar pill) were hospitalized due to PAH.

Disease progression included the need for injectable PAH medication or other worsening of PAH (decreased 6-minute walk distance [6MWD], PAH symptoms getting worse, and the need for new PAH treatment). Disease progression can also include less frequent instances of death, or the need for atrial septostomy (a procedure where a hole is placed between the two small chambers of the heart) or lung transplant.

The most common side effects occurring more frequently (≥3%) for patients taking OPSUMIT® vs patients taking placebo (sugar pill) were low red blood cell levels (anemia), stuffy nose or sore throat, irritation of the airways (bronchitis), headache, flu, and urinary tract infection.

OPSUMIT® helped patients walk farther

Treatment effect on 6MWT at Month 6:



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

Important Safety Information (continued)
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.

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OPSUMIT® (macitentan) improved patients’ functional class

More patients taking OPSUMIT® saw an improvement in functional class (measured by improvement of at least one functional class), which can mean less chest pain, less fatigue, and less shortness of breath.

Improvement in functional class from baseline to Month 6:

- ▶ 22% in patients receiving 10 mg OPSUMIT® (n=242) (vs 13% with placebo [sugar pill] [n=249])

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. According to PAH experts, maintaining or improving functional class is often an important goal of PAH treatment. Improved functional class means you can do more physical activity with fewer limitations. It does not always mean symptom improvement.

Important Safety Information (continued)
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



To learn more about the clinical trial resulting in less chance of PAH progression, scan this QR code using your smart phone or device.

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POSSIBLE SIDE EFFECTS

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Possible Side Effects

Here are possible side effects for OPSUMIT® (macitentan). This also includes side effects reported from a clinical study by 242 patients taking OPSUMIT® compared to 250 patients taking a placebo (sugar pill) for an average of 2 years.

Serious Side Effects Include

- 

Serious birth defects if taken during pregnancy
Females must not be pregnant when they start taking OPSUMIT® or become pregnant during treatment with OPSUMIT®. See “The most important information about OPSUMIT®” on pages 18-19.
- 

Liver problems
Incidence of elevated liver enzymes (liver enzyme counts more than 3 times the normal range).
Reported by ~3% of OPSUMIT® patients vs ~5% of patients taking a placebo (sugar pill)
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.
Reported by ~22% of OPSUMIT® patients vs ~21% of patients taking a placebo (sugar pill)
- 

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®.
Reported by ~13% of OPSUMIT® patients vs ~3% of patients taking a placebo (sugar pill)
- 

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.

Most Common Side Effects Include

- 

Stuffy nose or sore throat
Some people taking OPSUMIT® (macitentan) had cold-like symptoms.
Reported by ~20% of OPSUMIT® patients vs ~13% of patients taking a placebo (sugar pill)
- 

Irritation of the airways (also called bronchitis)
While taking OPSUMIT®, some patients noticed coughing or wheezing.
Reported by ~12% of OPSUMIT® patients vs ~6% of patients taking a placebo (sugar pill)
- 

Headache
Some people experience headaches while taking OPSUMIT®.
Reported by ~14% of OPSUMIT® patients vs ~9% of patients taking a placebo (sugar pill)
- 

Flu
Some people taking OPSUMIT® got the flu. Symptoms can include fever, body aches, and other common flu symptoms.
Reported by ~6% of OPSUMIT® patients vs ~2% of patients taking a placebo (sugar pill)
- 

Urinary tract infection (UTI)
A UTI is a very common type of infection. Patients on OPSUMIT® have a higher chance of getting a UTI.
Reported by ~9% of OPSUMIT® patients vs ~6% of patients taking a placebo (sugar pill)
Here are some warning signs:
 - Pain or burning during urination
 - Fever
 - Tiredness
 - Frequent urination
 - Abnormal urine that smells bad or is cloudy or red
 - Pain in your back or sides

Let your healthcare team know as soon as you experience any side effects, especially if they do not go away. The earlier you do, the sooner they can help you manage them. These are not all the possible side effects of OPSUMIT®. For more information, ask your doctor or pharmacist.
You may report side effects to the FDA at **1-800-FDA-1088** or **www.fda.gov/medwatch**.

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PAH Companion withMe

Personalized support for you

Everyone faces PAH differently. Once you and your doctor have decided that a PAH medicine by Johnson & Johnson is right for you, you can join PAH Companion withMe—a suite of patient support resources personalized just for you. You'll receive one-on-one educational support to help with your prescribed PAH medicine by Johnson & Johnson, plus customized tools and resources to help you take a more active role in your care.

When you participate in PAH Companion withMe, you'll have access to:

My PAH Companion

Support from your dedicated PAH Companion through one-on-one educational conversations. Your PAH Companion will communicate with you via phone, email, or text—whatever works best for you.

My Resources

Educational resources to help with your prescribed PAH medicine by Johnson & Johnson, tailored to your specific needs, questions, and interests.

My Tips

Ongoing support and education on living with PAH to help you partner with your healthcare team and engage with your support network.

My Community

Connection to current PAH information, peer support groups, and digital tools to help you take a more active role in your care.

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THE END OF YOUR GUIDE, BUT NOT YOUR JOURNEY.



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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 should have a negative pregnancy test before starting OPSUMIT®. Your doctor will decide when you should take pregnancy tests.

You are 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 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

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

You're Not Alone.



For information on paying for OPSUMIT®, call a J&J withMe Care Coordinator at **866-228-3546** Mon-Fri, 8 AM-8 PM ET



For support on living with PAH, talk with a trained, dedicated PAH Companion. You can learn more about PAH Companion withMe by calling **866-300-1818** Mon-Fri, 8 AM-9 PM ET

Learn more at pahcompanion.com



For more information, visit opsumit.com

The support and resources provided by PAH Companion withMe are not intended to provide medical advice, replace a treatment plan you receive from your doctor or nurse, or serve as a reason for you to start or stay on treatment.

Important Safety Information (continued)

-  **Before starting OPSUMIT®, during treatment, and for one month after stopping OPSUMIT®, women who are able to get pregnant should use effective 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.
-  **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.
-  If you are a woman who is able to get pregnant, you should talk to your doctor to learn the benefits and risks of OPSUMIT®.

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.

Important Safety Information (continued)

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 the FDA at **1-800-FDA-1088** or **www.fda.gov/medwatch**.

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Steps to Expect:

Now that you’ve received your medication, there are a couple of additional PAH resources Johnson & Johnson offers to help you continue treatment.



Connect With Your PAH Companion

Your dedicated PAH Companion will call you to learn more about you and put together personalized educational resources based on your needs and daily life. Your PAH Companion can connect you to support groups, virtual educational webinars, digital tools to monitor and track your health, and the latest PAH resources.

Your PAH Companion will call you from this number:
866-300-1818, Monday-Friday, 8 AM-9 PM ET

Learn more at pahcompanion.com



A Benefits Investigation Call from Your J&J withMe Care Coordinator

A J&J withMe Care Coordinator will call to go over the results of your Benefits Investigation, including estimated co-pay and financial support options.

A J&J withMe Care Coordinator will call you from this number:
866-228-3546, Monday-Friday, 8 AM-8 PM ET



Data rates may apply.

Important Contact Information

Make sure that you scan the QR code using the camera on your smartphone and that your phone is connected to the internet. This will ensure that the contact information is added directly to your contacts and will also help you identify when your Care Team is calling you. If you don’t have a smartphone, we encourage you to manually input and save the contact information above to your phone.

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