

One pill.
Two proven
PAH treatments.

Together for
memories that matter.




Opsynvi[®]
macitentan/tadalafil
10 mg/40 mg tablets

*Actor portrayal

What is OPSYNVI[®] (macitentan and tadalafil)?

OPSYNVI[®] is a prescription medicine that contains 2 medicines called macitentan and tadalafil. OPSYNVI[®] is used for long-term treatment of adults with pulmonary arterial hypertension (PAH), which is high blood pressure in the arteries of your lungs.

It is not known if OPSYNVI[®] is safe and effective in children.

SELECT IMPORTANT SAFETY INFORMATION

The most important information about OPSYNVI[®] (macitentan and tadalafil)

Do not take OPSYNVI[®] if you are pregnant or trying to get pregnant.

OPSYNVI[®] can cause serious birth defects if taken during pregnancy. Females who are able to get pregnant must use 2 acceptable forms of birth control during treatment with OPSYNVI[®], and for 1 month after stopping OPSYNVI[®]. If you have had a tubal sterilization, have a progesterone implant, or have an IUD (intrauterine device), you do not need a second form of birth control. Talk to your doctor or gynecologist about which birth control to use while on OPSYNVI[®].

Please read Important Safety Information throughout and on pages 12-14. Please [click here](#) to read Full Prescribing Information, including Serious Warning, and [click here](#) to read the Medication Guide for OPSYNVI[®] and discuss any questions you have with your doctor.

SELECT IMPORTANT SAFETY INFORMATION

What is the most important information I should know about OPSYNVI® (macitentan and tadalafil)?

OPSYNVI® can cause serious birth defects if taken during pregnancy. Females must not be pregnant when they start taking OPSYNVI® or become pregnant during treatment with OPSYNVI® or for 1 month after stopping treatment with OPSYNVI®.

Females who are able to get pregnant must have a negative pregnancy test before beginning treatment, each month during treatment and for 1 month after stopping treatment with OPSYNVI®. Your doctor will decide when to do the pregnancy test.

- Females who are able to get pregnant are females who:
 - have entered puberty, even if they have not started their menstrual period, **and**
 - have a uterus, **and**
 - have not gone through menopause. Menopause means that you have not had a menstrual period for at least 12 months for natural reasons, or that you have had your ovaries removed
- Females who are not able to get pregnant are females who:
 - have not yet entered puberty, **or**
 - do not have a uterus, **or**
 - have gone through menopause. Menopause means that you have not had a menstrual period for at least 12 months for natural reasons, or that you have had your ovaries removed, **or**

- are infertile for other medical reasons and this infertility is permanent and cannot be reversed

Females who are able to get pregnant must use 2 acceptable forms of birth control during treatment with OPSYNVI®, and for 1 month after stopping OPSYNVI® because the medicine may still be in the body. If you have had a tubal sterilization, have a progesterone implant, or have an IUD (intrauterine device), these methods can be used without another form of birth control. Talk with your doctor or gynecologist (a doctor who specializes in female reproduction) to find out about options for acceptable birth control that you may use to prevent pregnancy during treatment with OPSYNVI®. If you decide that you want to change the form of birth control that you use, talk with your doctor or gynecologist to be sure that you choose another acceptable form of birth control. **Also review the Medication Guide for acceptable birth control options.**

Do not have unprotected sex. Talk to your doctor or pharmacist right away if you have unprotected sex or if you think your birth control has failed. Your doctor may talk with you about using emergency birth control.

Tell your doctor right away if you miss a menstrual period or think you may be pregnant.

Females can only receive OPSYNVI® through a restricted program called the Macitentan-Containing Products Risk Evaluation and Mitigation Strategy (REMS). If you are a female who can get pregnant, you must talk to your doctor, understand the benefits and risks of OPSYNVI®, and agree to all of the instructions in the Macitentan-Containing Products REMS. Males can receive OPSYNVI® without taking part in the Macitentan-Containing Products REMS.

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With a PAH portfolio spanning decades of experience,
Johnson & Johnson remains committed to serving people living with PAH.



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IMPORTANT SAFETY
INFORMATION

*Actor portrayal



*Actor portrayal

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IMPORTANT SAFETY
INFORMATION

SELECT IMPORTANT SAFETY INFORMATION (continued)

Who should not take OPSYNVI® (macitentan and tadalafil)?

Do not take OPSYNVI® if you:

- are pregnant, plan to become pregnant, or become pregnant during treatment with OPSYNVI®. OPSYNVI® can cause serious birth defects (see “What is the most important information I should know about OPSYNVI®?”)
- are allergic to macitentan, tadalafil, or any of the ingredients in OPSYNVI®. Review the Medication Guide for a complete list of ingredients in OPSYNVI®

Please read Important Safety Information throughout and on pages 12-14. Please [click here](#) to read Full Prescribing Information, including Serious Warning, and [click here](#) to read the Medication Guide for OPSYNVI® and discuss any questions you have with your doctor.



A **first-of-its-kind** treatment combining macitentan and tadalafil in a once-daily pill.



Combination therapy with macitentan and tadalafil is a clinical guideline* recommendation for PAH treatment.

Clinical guidelines are evidence-based recommendations that assist healthcare providers in diagnosing and treating a medical condition.

Dual combination treatment with macitentan and tadalafil is a guideline recommendation for the initial treatment of pulmonary arterial hypertension (PAH), for patients with certain types of PAH[†] who do not have other conditions of the heart and lungs.

*2022 European Society of Cardiology/European Respiratory Society Guidelines

[†]Cause unknown (idiopathic), heritable, drug-related PAH, or PAH linked to connective tissue disease.

To learn more about PAH visit [OPSYNVI.com](https://www.opsynvi.com)

SELECT IMPORTANT SAFETY INFORMATION (continued)

Who should not take OPSYNVI® (macitentan and tadalafil)? (continued)

Do not take OPSYNVI® if you:

- take any medicines called nitrates
- take any medicines called guanylate cyclase (GC) stimulators

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The efficacy and safety of OPSYNVI® (macitentan and tadalafil) was studied in a clinical trial with 187 adults with PAH (WHO* Group I and WHO FC† II-III). PVR reduction was compared at 16 weeks between patients taking OPSYNVI® (n=108) versus those taking macitentan alone (n=35) and versus those taking tadalafil alone (n=44).

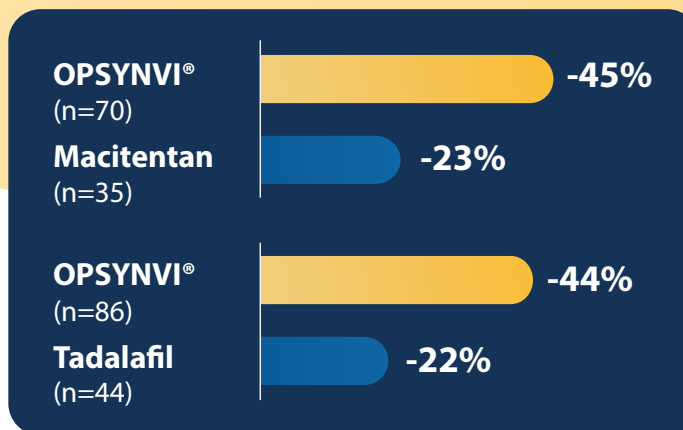
One pill, two proven treatments

OPSYNVI® helps you target two foundational PAH pathways with a single pill.

OPSYNVI® was proven to have greater reductions in pulmonary vascular resistance (PVR)[§] than tadalafil or macitentan alone.

The **key findings** of this study showed that OPSYNVI® resulted in a **29%** greater reduction in PVR versus macitentan alone, and a **28%** greater reduction versus tadalafil alone.

Percent PVR Reductions from start of study to week 16



* WHO = World Health Organization

† FC = Functional Class

§ PVR is the resistance that blood flow encounters as it flows through the blood vessels in the lungs and to the upper left side of your heart. PVR is measured in $\text{dyn} \times \text{s}/\text{cm}^5$.

SELECT IMPORTANT SAFETY INFORMATION (continued)

Before taking OPSYNVI®, tell your doctor about all of your medical conditions, including if you:

- have liver problems
- have low blood pressure
- have low red blood cell levels (anemia)
- have heart problems including heart attack or heart failure
- have narrowing of the pulmonary veins (veins in your lungs). This is called pulmonary veno-occlusive disease (PVOD)

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OPSYNVI® Safety Profile

The nature of the side effects was consistent with each of the individual components, macitentan and tadalafil, alone.



Side Effects


The side effects ($\geq 3\%$) of OPSYNVI® include too much fluid in your body and swelling caused by too much fluid, low red blood cell levels, headache/migraine, abdominal pain, low blood pressure, muscle pain, nasal congestion, nausea, increased uterine bleeding, back pain, temporary reddening of the skin, vomiting, heart palpitations, pain in arms or legs, and nose bleed.



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*Actor portrayal

A close-up photograph of a person's hands painting a vibrant, abstract artwork on a canvas. The person is wearing a blue denim jacket over a light-colored shirt. They are holding a paintbrush with a wooden handle and a metal ferrule, applying blue paint to the canvas. The artwork features bold, curved bands of color including blue, yellow, red, and green. In the background, another person's hands are visible, holding a yellow bowl and a brush, suggesting a collaborative or instructional setting.

Learn more on how to take OPSYNVI® (macitentan and tadalafil) [here](#).

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SELECT IMPORTANT SAFETY INFORMATION (continued)

Before taking OPSYNVI®, tell your doctor about all of your medical conditions, including if you: (continued)

- have any eye problems, including non-arteritic anterior ischemic optic neuropathy (NAION) or an inherited eye disorder called retinitis pigmentosa
- have hearing problems such as ringing in the ears, dizziness, or loss of hearing
- have a deformed penis shape or Peyronie's disease or have blood cell problems such as sickle cell anemia, multiple myeloma, or leukemia. These conditions increase your risk of getting a prolonged erection.

Please read Important Safety Information throughout and on pages 12-14. Please [click here](#) to read Full Prescribing Information, including Serious Warning, and [click here](#) to read the Medication Guide for OPSYNVI® and discuss any questions you have with your doctor.

IMPORTANT SAFETY
INFORMATION

Manage your PAH without managing more prescriptions

OPSYNVI® (macitentan and tadalafil) is a once-daily pill with a dual-pathway approach.

If you are **not currently on** any PAH therapy or are transitioning from an ERA alone:



One OPSYNVI® pill (macitentan 10mg/tadalafil 20mg), once daily for 1 week.



If tolerated, the doctor will increase your dose to one OPSYNVI® pill (macitentan 10mg/tadalafil 40mg), once daily.

ERA = endothelin receptor antagonists

If you are **transitioning from** a PDE5i alone or taking the combination of an ERA and a PDE5i as individual pills:



Start with one OPSYNVI® pill (macitentan 10mg/tadalafil 40mg), once daily.

PDE5i = phosphodiesterase type 5 inhibitor

The pills illustrated above are not actual size.

SELECT IMPORTANT SAFETY INFORMATION (continued)

Before taking OPSYNVI®, tell your doctor about all of your medical conditions, including if you: (continued)

- have kidney problems or get dialysis
- are pregnant or plan to become pregnant during OPSYNVI® treatment. OPSYNVI® can cause serious birth defects.
- are breastfeeding or plan to breast feed. It is not known if OPSYNVI® passes into your breastmilk. **Do not** breastfeed during treatment with OPSYNVI®.

Please read Important Safety Information throughout and on pages 12-14. Please [click here](#) to read Full Prescribing Information, including Serious Warning, and [click here](#) to read the Medication Guide for OPSYNVI® and discuss any questions you have with your doctor.

Learn about more support resources [here](#).

LEARN ABOUT OPSYNVI®

START OPSYNVI®

IMPORTANT SAFETY
INFORMATION

You're **not alone** on your treatment journey.

With a PAH portfolio spanning decades of experience, Johnson & Johnson remains committed to serving people living with PAH. We also offer a variety of educational resources and patient support programs to assist you along the way.

*Actor portrayal

3 steps to get started on OPSYNVI®

Step 1: J&J withMe will call you with cost support options

J&J withMe will give you information on your insurance coverage, potential out-of-pocket costs, options to make your treatment more affordable, and treatment support.

Learn more about J&J withMe at [JNJwithMe.com](https://www.JNJwithMe.com).

Step 2: Coordinate with your Specialty Pharmacy to help prevent medication delays

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: Join PAH Companion withMe* for personalized 1:1 support

- Over **10,000** patients have found support with a dedicated PAH Companion
- **94%** of enrolled patients recommend the PAH Companion withMe program

If you've been prescribed OPSYNVI® (macitentan and tadalafil), you can learn more about PAH Companion withMe by calling 866-300-1818, Monday-Friday, 8 AM-9 PM ET.

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.

*PAH Companion withMe requires a completed patient authorization form to enroll.

J&J withMe Care Coordinator:
866-228-3546, Monday-Friday, 8 AM-8 PM ET.

PAH Companion withMe:
866-300-1818, Monday-Friday, 8 AM-9 PM ET.

INDICATION

What is OPSYNVI® (macitentan and tadalafil)?

OPSYNVI® is a prescription medicine that contains 2 medicines called macitentan and tadalafil. OPSYNVI® is used for long-term treatment of adults with pulmonary arterial hypertension (PAH), which is high blood pressure in the arteries of your lungs.

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

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about OPSYNVI® (macitentan and tadalafil)?

OPSYNVI® can cause serious birth defects if taken during pregnancy. Females must not be pregnant when they start taking OPSYNVI® or become pregnant during treatment with OPSYNVI® or for 1 month after stopping treatment with OPSYNVI®.

Females who are able to get pregnant must have a negative pregnancy test before beginning treatment, each month during treatment and for 1 month after stopping treatment with OPSYNVI®. Your doctor will decide when to do the pregnancy test.

- Females who are able to get pregnant are females who:
 - have entered puberty, even if they have not started their menstrual period, **and**
 - have a uterus, **and**
 - have not gone through menopause. Menopause means that you have not had a menstrual period for at least 12 months for natural reasons, or that you have had your ovaries removed

- Females who are not able to get pregnant are females who:
 - have not yet entered puberty, **or**
 - do not have a uterus, **or**
 - have gone through menopause. Menopause means that you have not had a menstrual period for at least 12 months for natural reasons, or that you have had your ovaries removed, **or**
 - are infertile for other medical reasons and this infertility is permanent and cannot be reversed

Females who are able to get pregnant must use 2 acceptable forms of birth control during treatment with OPSYNVI®, and for 1 month after stopping OPSYNVI® because the medicine may still be in the body. If you have had a tubal sterilization, have a progesterone implant, or have an IUD (intrauterine device), these methods can be used without another form of birth control. Talk with your doctor or gynecologist (a doctor who specializes in female reproduction) to find out about options for acceptable birth control that you may use to prevent pregnancy during treatment with OPSYNVI®. If you decide that you want to change the form of birth control that you use, talk with your doctor or gynecologist to be sure that you choose another acceptable form of birth control. **Also review the Medication Guide for acceptable birth control options.**

Do not have unprotected sex. Talk to your doctor or pharmacist right away if you have unprotected sex or if you think your birth control has failed. Your doctor may talk with you about using emergency birth control.

Tell your doctor right away if you miss a menstrual period or think you may be pregnant.

Females can only receive OPSYNVI® through a restricted program

IMPORTANT SAFETY INFORMATION (continued)

called the Macitentan-Containing Products Risk Evaluation and Mitigation Strategy (REMS). If you are a female who can get pregnant, you must talk to your doctor, understand the benefits and risks of OPSYNVI®, and agree to all of the instructions in the Macitentan-Containing Products REMS. Males can receive OPSYNVI® without taking part in the Macitentan-Containing Products REMS.

Who should not take OPSYNVI® (macitentan and tadalafil)?

Do not take OPSYNVI® if you:

- are pregnant, plan to become pregnant, or become pregnant during treatment with OPSYNVI®. OPSYNVI® can cause serious birth defects (see “What is the most important information I should know about OPSYNVI®?”)
- are allergic to macitentan, tadalafil, or any of the ingredients in OPSYNVI®. Review the Medication Guide for a complete list of ingredients in OPSYNVI®
- take any medicines called nitrates
- take any medicines called guanylate cyclase (GC) stimulators

Before taking OPSYNVI®, tell your doctor about all of your medical conditions, including if you:

- have liver problems
- have low blood pressure
- have low red blood cell levels (anemia)
- have heart problems including heart attack or heart failure
- have narrowing of the pulmonary veins (veins in your lungs). This is called pulmonary veno-occlusive disease (PVOD)
- have any eye problems, including non-arteritic anterior ischemic optic neuropathy (NAION) or an inherited eye disorder called retinitis pigmentosa

- have hearing problems such as ringing in the ears, dizziness, or loss of hearing
- have a deformed penis shape or Peyronie’s disease or have blood cell problems such as sickle cell anemia, multiple myeloma, or leukemia. These conditions increase your risk of getting a prolonged erection
- have kidney problems or get dialysis
- are pregnant or plan to become pregnant during OPSYNVI® treatment. OPSYNVI® can cause serious birth defects
- are breastfeeding or plan to breast feed. It is not known if OPSYNVI® passes into your breastmilk. **Do not** breastfeed during treatment with OPSYNVI®

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking OPSYNVI® with other medicines may affect the way OPSYNVI® and the other medicines work, and may increase your risk of side effects. **Do not** start any new medicine until you check with your doctor. Especially tell your doctor if you take:

- nitrate medicines
- HIV medicines
- antifungal medicines
- antiseizure medicines
- medicines used to treat infection
- erectile dysfunction medicines
- blood pressure medicines
- medicines used to treat PAH or heart problems

Ask your doctor or pharmacist if you are not sure if your medicine is one that is listed above. Know the medicines you take. Keep a list and show it to your doctor or pharmacist when you get a new medicine.

What should I avoid while taking OPSYNVI®?

Do not have more than 4 alcohol-containing drinks in a short period of time during treatment with OPSYNVI®. Drinking too much alcohol can increase your chances of getting low blood pressure, increased heart rate, dizziness and headache.

IMPORTANT SAFETY INFORMATION (continued)

What are the possible side effects of OPSYNVI® (macitentan and tadalafil)?

OPSYNVI® can cause serious side effects, including:

- **Serious birth defects.** See “What is the most important information I should know about OPSYNVI®?”
- **Liver problems.** OPSYNVI® can cause liver problems. Your doctor should do blood tests to check your liver before you start taking OPSYNVI®. Tell your doctor if you have any of the following symptoms of liver problems during treatment with OPSYNVI®:
 - nausea or vomiting
 - yellowing of your skin or whites of your eyes
 - pain in the upper right stomach
 - dark urine
 - fever
 - tiredness
 - itching
 - loss of appetite
- **Decreased blood pressure (hypotension).** OPSYNVI® can cause low blood pressure that lasts for a short time
- **Low red blood cell levels (anemia) can occur with OPSYNVI® treatment, usually during the first weeks after starting therapy.** Your doctor will do blood tests to check your red blood cells before starting and as needed during treatment with OPSYNVI®
- **Vision loss.** OPSYNVI® can cause decreased eyesight or permanent loss of vision in 1 or both eyes, which could be a sign of NAION. There is an increased risk of NAION in people who have already had NAION in 1 eye. If you notice a sudden decrease or loss of vision in 1 or both eyes, contact your doctor right away
- **Hearing problems.** Sudden decrease or loss of hearing, sometimes with ringing in the ears and dizziness, can happen during treatment with OPSYNVI®. If you notice a sudden decrease or loss of hearing, contact your doctor right away

- **Fluid retention.** Fluid retention can happen within weeks after starting OPSYNVI® and could lead to hospitalization. Tell your doctor right away if you have any unusual weight gain, trouble breathing, or swelling of your ankles or legs. Your doctor will look for the cause of any fluid retention and may stop treatment with OPSYNVI®
- **Decreased sperm count.** OPSYNVI® can cause decreased sperm counts in males and may affect the ability to father a child. Tell your doctor if being able to have children is important to you
- **Prolonged erection.** Erections that last more than 4 hours, with or without pain, can happen during treatment with OPSYNVI®. Painful erections (priapism) can cause permanent damage to the penis if not treated right away. Tell your doctor right away if you have an erection that lasts longer than 4 hours, with or without pain

The most common side effects of OPSYNVI® include:

- too much fluid in your body (fluid retention) and swelling caused by too much fluid (edema)
- low red blood cell levels (anemia)
- headache, including migraine headache

These are not all the possible side effects of OPSYNVI®. Call your doctor for medical advice about side effects. You may report side effects to FDA at **1-800-FDA-1088** or **www.fda.gov/medwatch**.

Please read full [Prescribing Information](#), including Boxed Warning, and [Medication Guide](#) for OPSYNVI® and discuss any questions you have with your doctor.

cp-443045v1



*Actor portrayal

Take on PAH with more information [here](#)

Learn more about the benefits of **combination therapy** with OPSYNVI®

* Actor portrayal

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