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PATIENT & CAREGIVER EDUCATION

# Macitentan and Tadalafil

This information from Lexicomp® explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

## Brand Names: Canada

Opsynvi

## What is this drug used for?

- It is used to treat high blood pressure in the lungs.

## What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have been told that your body has problems with certain sugars (lactose, glucose, galactose). Some products have lactose.
- If you have certain hereditary eye problems like retinitis pigmentosa.
- If you have ever had an eye problem called non-arteritic anterior ischemic optic neuropathy (NAION).
- If you have any of these health problems: Anemia, kidney disease, or liver disease.
- If you have a health problem called pulmonary veno-occlusive disease (PVOD).
- If you are taking riociguat.

- If you use drugs called “poppers” like amyl nitrite and butyl nitrite.
- If you are taking any of these drugs: Isosorbide dinitrate, isosorbide mononitrate, or nitroglycerin. Do not take these drugs with this drug. You may also need to avoid taking these drugs for some time after your last dose of this drug.
- If you take any drugs (prescription or OTC, natural products, vitamins) that must not be taken with this drug, like certain drugs that are used for HIV, infections, or seizures. There are many drugs that must not be taken with this drug.
- If you are taking another drug like this one that is used to treat erectile dysfunction (ED) or high pressure in the lungs.
- If you are pregnant or may be pregnant. Do not take this drug if you are pregnant.
- If you are breast-feeding. Do not breast-feed while you take this drug.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

## **What are some things I need to know or do while I take this drug?**

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug affects you.
- To lower the chance of feeling dizzy or passing out, rise slowly if you have been sitting or lying down. Be careful going up and down stairs.
- Have blood work checked as you have been told by the doctor. Talk with

the doctor.

- Check your blood pressure as you have been told.
- Talk with your doctor before you drink alcohol.
- If you drink grapefruit juice or eat grapefruit often, talk with your doctor.
- Very bad and sometimes deadly side effects like a heartbeat that does not feel normal, heart attack, stroke, and very bad high blood pressure have happened with tadalafil. Talk with the doctor.
- A very bad eye problem has rarely happened with this drug. This may lead to a change in eyesight and sometimes loss of eyesight, which may not come back. Talk with the doctor.
- Low red blood cell levels have happened with this drug. Sometimes, this has led to anemia and the need for a blood transfusion. If you have anemia or have been told that you have a low red blood cell level, talk with your doctor.
- This drug may lower sperm counts. This may affect being able to father a child. If you have questions, talk with the doctor.
- This drug may cause harm to an unborn baby. A pregnancy test will be done before you start this drug to show that you are NOT pregnant.
- If you may become pregnant, you must use birth control while taking this drug and for some time after the last dose. Ask your doctor how long to use birth control. If you get pregnant, call your doctor right away.

## **What are some side effects that I need to call my doctor about right away?**

**WARNING/CAUTION:** Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual

hoarseness; or swelling of the mouth, face, lips, tongue, or throat.

- Signs of liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Signs of a urinary tract infection (UTI) like blood in the urine, burning or pain when passing urine, feeling the need to pass urine often or right away, fever, lower stomach pain, or pelvic pain.
- Trouble breathing that is new or worse.
- Shortness of breath, a big weight gain, or swelling in the arms or legs.
- Dizziness or passing out.
- Chest pain.
- Cough.
- Change in eyesight, eye pain, or severe eye irritation.
- Loss of eyesight.
- Ringing in the ears, hearing loss, or any other changes in hearing.
- Memory problems or loss.
- Call your doctor right away if you have a painful erection (hard penis) or an erection that lasts for longer than 4 hours. This may happen even when you are not having sex. If this is not treated right away, it may lead to lasting sex problems and you may not be able to have sex.

## **What are some other side effects of this drug?**

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Headache.
- Muscle pain.
- Back pain.
- Pain in arms or legs.

- Constipation, diarrhea, stomach pain, upset stomach, or throwing up.
- Nose or throat irritation.
- Signs of a common cold.
- Flu-like signs.
- Flushing.
- Feeling tired or weak.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1-800-332-1088. You may also report side effects at <https://www.fda.gov/medwatch>.

## **How is this drug best taken?**

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- Take with or without food.
- Swallow whole. Do not chew, break, or crush.
- Take this drug at the same time of day.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.

## **What do I do if I miss a dose?**

- Take a missed dose as soon as you think about it.
- If you do not think about the missed dose until the next day, skip the missed dose and go back to your normal time.
- Do not take 2 doses on the same day.

## How do I store and/or throw out this drug?

- Store at room temperature in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

## General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- Some drugs may have another patient information leaflet. Check with your pharmacist. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

## Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based

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If you have any questions, contact a member of your care team directly. If you're a patient at MSK and you need to reach a provider after 5 p.m., during the weekend, or on a holiday, call 212-639-2000.

For more resources, visit [www.mskcc.org/pe](http://www.mskcc.org/pe) to search our virtual library.

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