PATIENT & CAREGIVER EDUCATION

Macitentan and Tadalafil

This information from UpToDate® Lexidrug™ 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: US

Opsynvi

Brand Names: Canada

Opsynvi

Warning

- This drug may cause harm to the unborn baby if you take it while you are pregnant.
- Do not take this drug if you are pregnant. A pregnancy test will be done to show that you are NOT pregnant before starting this drug.
- If you may become pregnant, you must use birth control before starting this drug, while you are taking it, and for 1 month after you stop this drug. Talk with your doctor about what type(s) of birth control to use with this drug.
- If you get pregnant or think you may be pregnant, call your doctor right away.
- If you miss a period, have unprotected sex, or think that your birth control has not worked, call your doctor right away.

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 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 anemia.
- If you have kidney disease.
- If you have liver disease or raised liver enzymes.
- If you have a health problem called pulmonary veno-occlusive disease (PVOD).
- If you are taking riociguat or vericiguat.
- 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 other drugs (prescription or OTC, natural products, vitamins). There are many drugs that interact with this drug, like certain drugs that are used for HIV, infections, and other health problems.
- If you are taking another drug that has the same drug in

it.

- 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 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?

For all patients taking 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 your blood work and other lab tests checked as you have been told by your 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.
- Severe and sometimes deadly side effects like an abnormal heartbeat, heart attack, stroke, and severe 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.
- Swelling and extra fluid in the body have happened with this drug. Some people have had to take other drugs to

treat this. Sometimes, people have had to go to the hospital to be treated for heart failure. Talk with the doctor.

- This drug may lower sperm counts. This may affect being able to father a child. If you have questions, talk with the doctor.

Children:

- If your child started taking this drug before puberty, talk with the doctor. Call the doctor right away if breast buds or pubic hair begin to develop or if your child's period starts.

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 severe skin reaction (Stevens-Johnson syndrome) like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in the mouth, throat, nose, or eyes.
- Shortness of breath, a big weight gain, or swelling in the arms or legs.
- Dizziness or passing out.
- Feeling very tired or weak.
- Change in eyesight, eye pain, or severe eye irritation.
- Loss of eyesight.
- Ringing in the ears, hearing loss, or any other changes in hearing.
- 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.
- Stomach pain.
- Upset stomach.
- Nose or throat irritation.
- Flushing.

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 with a full glass of water.
- 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 at the same time or extra doses.

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

- Store in the original container at room temperature.
- Store in a dry place. Do not store in a bathroom.
- If this drug comes in a bottle, keep the lid tightly closed. Each bottle has a desiccant packet (protects the drug

from moisture). Keep the desiccant in the bottle. Do not eat the desiccant.

- 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.
- This drug comes with an extra patient fact sheet called a Medication Guide. Read it with care. Read it again each time this drug is refilled. If you have any questions about this drug, please talk with the doctor, 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 on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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