

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **OPSUMIT**[®]

Macitentan Tablets

Read this carefully before you start taking **OPSUMIT**[®] and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **OPSUMIT**[®].

Serious Warnings and Precautions

- Serious birth defects
- Anemia (reduced number of red blood cells)

What is **OPSUMIT**[®] used for?

OPSUMIT[®] is used to treat certain types of pulmonary arterial hypertension (PAH). It can be taken on its own or with other PAH medications as prescribed by your health care provider.

How does **OPSUMIT**[®] work?

OPSUMIT[®] is an endothelin receptor antagonist (ERA). It works by lowering high blood pressure in your lungs. This makes it easier for your heart to pump blood through the pulmonary arteries and can help lower the chance of your disease getting worse.

What are the ingredients in **OPSUMIT**[®]?

Medicinal ingredient: Macitentan

Non-medicinal ingredients: Lactose monohydrate, magnesium stearate, microcrystalline cellulose, polysorbate 80, polyvinyl alcohol, povidone, sodium starch glycolate Type A, soya lecithin, talc, titanium dioxide and xanthan gum.

OPSUMIT[®] comes in the following dosage forms:

Tablets: 10 mg

Do not use **OPSUMIT**[®] if you:

- are allergic to macitentan or any of the other ingredients in **OPSUMIT**[®] (see “**What are the ingredients in OPSUMIT**[®]”).
- are pregnant, think you are pregnant, plan to become pregnant, or could become pregnant because you are not using reliable birth control. If you think you are pregnant or get pregnant while taking **OPSUMIT**[®], tell your doctor right away.
- are breastfeeding or plan to breastfeed. It is not known if **OPSUMIT**[®] can pass through your breast milk and harm your baby.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take OPSUMIT[®]. Talk about any health conditions or problems you may have, including if you:

- have low red blood cell levels (anemia).
- have liver problems.

- have kidney problems.
- are breastfeeding, or plan to breastfeed. It is not known whether OPSUMIT[®] is excreted into your breast milk.
- are or are planning on becoming pregnant. OPSUMIT[®] can cause serious birth defects if taken during pregnancy.

Other warnings you should know about:

- Do not take OPSUMIT[®] if you are pregnant. Talk to your doctor if you become pregnant while on treatment.
- Females who are able to get pregnant must take a pregnancy test before starting OPSUMIT[®]. Monthly pregnancy tests during treatment with OPSUMIT[®] are recommended to allow the early detection of pregnancy.
- Do not get pregnant while you are taking OPSUMIT[®]. Talk with your doctor or gynecologist (a doctor who specializes in female reproduction) to find out about how to prevent pregnancy.
- Do not have unprotected sex. Tell your doctor right away if you have unprotected sex. Tell your doctor right away if you think your birth control has failed.
- If you become pregnant, call your doctor right away. Stop taking OPSUMIT[®].
- Decreases in sperm count have been observed in drugs related to the current medication. Speak with your doctor if you plan on fathering a child.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with OPSUMIT[®]:

- rifampicin, clarithromycin, ciprofloxacin, erythromycin (antibiotics used to treat infection)
- ritonavir, saquinavir (used to treat HIV infection)
- nefazodone (used to treat depression)
- ketoconazole, itraconazole, fluconazole, miconazole, voriconazole (medicine used against fungal infection)
- amiodarone (medicine used to control heartbeat)
- cyclosporine (used to prevent organ rejection after transplant)
- diltiazem, verapamil (used to treat high blood pressure of specific heart problems)

How to take OPSUMIT[®]:

- Take OPSUMIT[®] exactly as your doctor tells you to take it
- It will be easier to remember to take OPSUMIT[®] if you take it at the same time each day
- Do not split, crush, or chew OPSUMIT[®] tablets
- Do not stop taking OPSUMIT[®] unless your doctor tells you to

Tests during Treatment:

Some patients taking OPSUMIT[®] were found to have abnormal liver function values (increase in liver enzymes) and some patients developed anemia (reduction in red blood cells). Because these findings may not cause symptoms you can feel or observe yourself, your doctor will do regular blood tests to assess any changes in your liver function and hemoglobin level.

Liver function:

This blood test will be done:

- prior to initiation of OPSUMIT®
- every month during the first year of treatment or more frequently, if needed

If you develop abnormal liver function, your doctor may decide to stop treatment with OPSUMIT®.

When your blood test results for liver function return to normal, your doctor may decide to restart treatment with OPSUMIT®.

Anemia:

This blood test will be done:

- prior to initiation of OPSUMIT®
- at one month after treatment start and as decided by doctor thereafter

If you develop anemia, your doctor may decide to perform further tests to investigate the cause.

Your regular blood tests, both for liver function and anemia, are an important part of your treatment.

Usual Dose:

Take one tablet once daily, with or without food.

Overdose:

If you think you, or a person you are caring for, have taken too much OPSUMIT®, contact a healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of OPSUMIT®, take your tablet as soon as you remember. Do not take 2 doses at the same time. If it is almost time for your next dose, skip the missed dose. Just take the next dose at your regular time.

What are possible side effects from using OPSUMIT®?

These are not all the possible side effects you may feel when taking OPSUMIT®. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Stuffy nose and congestion (nasopharyngitis)
- Headache
- Sore throat (pharyngitis)
- Flu (influenza)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON Anemia (decreased number of red blood cells): fatigue, loss of energy, irregular heartbeats, pale complexion, shortness of breath, weakness	✓		
Bronchitis (irritation of the airways): coughing, mucus production, fatigue, shortness of breath, slight fever and chills, chest discomfort	✓		
Edema: unusual swelling of the arms, hands, legs, feet and ankles, face or airway passages	✓		
COMMON Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up)	✓		
Urinary tract infection (infection in urinary system including kidneys, ureters, bladder and urethra): pain or burning sensation while urinating, frequent urination, blood in urine, pain in the pelvis, strong smelling urine, cloudy urine	✓		
KNOWN Hypersensitivity (allergic reaction): fever, skin rash, hives, itching, swelling, shortness of breath, wheezing, runny nose, itchy, watery eyes			✓
RARE Liver problems: yellowing of your skin and eyes (jaundice), right upper stomach area pain or swelling, fever, nausea or vomiting, unusual dark urine, unusual tiredness		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store OPSUMIT® tablets at room temperature between 15°C and 30°C.

Keep out of reach and sight of children.

- **If you want more information about OPSUMIT®:** Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.janssen.com/canada, or by calling 1-800-567-3331 or 1-800-387-8781.

This leaflet was prepared by Janssen Inc., Toronto Ontario, M3C 1L9

Last Revised: August 2021

© 2021 JANSSEN Inc.

All trademarks used under license.