

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[®]**.

What is OPSUMIT[®] used for?

OPSUMIT[®] is used in adults to treat certain types of pulmonary arterial hypertension (PAH), which is high blood pressure in the blood vessels leading to your lungs. It can be taken on its own or with other PAH medications as prescribed by your healthcare professional.

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 of macitentan.

Do not use OPSUMIT[®] if:

- you are allergic to macitentan or any of the other ingredients in **OPSUMIT[®]**.
- you are pregnant, think you are pregnant, plan to become pregnant, or could become pregnant because you are not using reliable birth control. **OPSUMIT[®]** can cause serious birth defects if taken during pregnancy. If you think you are pregnant or get pregnant while taking **OPSUMIT[®]**, tell your healthcare professional right away.
- you 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.
- have pulmonary veno-occlusive disease (PVOD), a condition where your blood vessels are blocked.

- are on dialysis

Other warnings you should know about:**Pregnancy:**

- Do not take OPSUMIT® if you are pregnant. Talk to your healthcare professional if you become pregnant while on treatment.
- If you are able to get pregnant, you 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 have unprotected sex. Tell your healthcare professional right away if you have unprotected sex, or if you think your birth control has failed.
- You should NOT get pregnant while you are taking OPSUMIT® or within 1 month after stopping your treatment. Talk with your healthcare professional or gynecologist (a healthcare professional who specializes in female reproduction) to find out about how to prevent pregnancy.
- If you become pregnant while taking OPSUMIT® or within 1 month after stopping your treatment, call your healthcare professional right away.

Fertility in Men:

- Decreases in sperm count have been observed with OPSUMIT® and related drugs. Speak with your healthcare professional if you plan on fathering a child.

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 healthcare professional 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 healthcare professional may decide to stop treatment with OPSUMIT®.

When your blood test results for liver function return to normal, your healthcare professional 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 healthcare professional thereafter.

If you develop anemia, your healthcare professional 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.

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®:

- Always take OPSUMIT® exactly as your healthcare professional tells you to. Check with your healthcare professional if you are not sure. Do not stop taking OPSUMIT® unless your healthcare professional tells you to
- Swallow the tablets whole. Do NOT break, crush, or chew the tablets.
- OPSUMIT® can be taken with or without food.
- Try to take OPSUMIT® at the same time each day.

Usual Dose:

The recommended dose of OPSUMIT® is one tablet once a day.

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, tell 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	✓		
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		✓	
UNKNOWN FREQUENCY			

Allergic reaction: fever, skin rash, hives, itching, swelling, shortness of breath, wheezing, runny nose, itchy, or watery eyes			✓
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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/adverse-reaction-reporting.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 healthcare 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

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