

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

Pr **OPSUMIT**<sup>®</sup>

#### **Macitentan Tablets**

This Patient Medication Information is written for the person who will be taking **OPSUMIT**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **OPSUMIT**, talk to a healthcare professional.

#### **What OPSUMIT is used for:**

OPSUMIT is used 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 OPSUMIT works:**

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.

#### **The ingredients in OPSUMIT are:**

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:**

Film-coated 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 film-coated tablets whole. Do NOT break, crush, or chew the film-coated 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 film-coated tablets is one 10 mg tablet once a day.

For dosing in children, lower strength dispersible tablets for suspension are available, please refer to the Patient Medication Information for OPSUMIT dispersible tablets for suspension (2.5 mg).

**Overdose:**

If you think you, or a person you are caring for, have taken too much OPSUMIT, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.
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**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.

**Possible side effects from using OPSUMIT**

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

Side effects may include:

- Itchy, runny or stuffy nose and congestion (nasopharyngitis);
- Headache;
- Sore throat (pharyngitis);
- Flu (influenza);
- Infected nose, sinuses or throat (upper respiratory tract infection);
- Inflamed stomach or gut (gastroenteritis);
- Increased or abnormal menstrual bleeding.

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>VERY COMMON</b>			
<b>Anemia</b> (decreased number of red blood cells): fatigue, loss of energy, irregular heartbeats, pale complexion, shortness of breath, weakness	✓		
<b>Bronchitis</b> (irritation of the airways): coughing, mucus production, fatigue, shortness of breath, slight fever and chills, chest discomfort	✓		
<b>Edema:</b> unusual swelling of the arms, hands, legs, feet and ankles, face or airway passages	✓		
<b>COMMON</b>			
<b>Hypotension</b> (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up)	✓		
<b>Urinary tract infection</b> (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	✓		
<b>RARE</b>			

<b>Liver problems:</b> yellowing of your skin and eyes (jaundice), right upper stomach area pain or swelling, fever, nausea or vomiting, unusual dark urine, unusual tiredness		✓	
<b>UNKNOWN FREQUENCY</b>			
<b>Allergic reaction:</b> fever, skin rash, hives, itching, swelling, shortness of breath, wheezing, runny nose, itchy, or watery eyes			✓

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.

<p><b>Reporting Side Effects</b></p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> <li>• Visiting the Web page on Adverse Reaction Reporting (<a href="http://canada.ca/drug-device-reporting">canada.ca/drug-device-reporting</a>) for information on how to report online, by mail or by fax; or</li> <li>• Calling toll-free at 1-866-234-2345.</li> </ul> <p><i>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.</i></p>
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**Storage:**

Store OPSUMIT 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 [innovativemedicine.jnj.com/canada](http://innovativemedicine.jnj.com/canada), or by calling 1-800-567-3331 or 1-800-387-8781.

This leaflet was prepared by Janssen Inc., a Johnson & Johnson company, Toronto Ontario, M3C 1L9

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## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

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#### **Macitentan Dispersible Tablets for Suspension**

This Patient Medication Information is written for the person who will be taking **OPSUMIT**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

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#### **What OPSUMIT is used for:**

OPSUMIT is used 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 OPSUMIT works:**

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.

#### **The ingredients in OPSUMIT are:**

Medicinal ingredient: Macitentan.

Non-medicinal ingredients: croscarmellose sodium, isomalt, magnesium stearate, mannitol

#### **OPSUMIT comes in the following dosage forms:**

Dispersible tablets for suspension: 2.5 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.
- OPSUMIT can be taken with or without food.
- Try to take OPSUMIT at the same time each day.
- Take OPSUMIT dispersible tablets as an oral suspension only:
  - OPSUMIT dispersible tablets must be mixed with drinking water to create a white cloudy liquid (known as an oral suspension).
  - The oral suspension can be prepared in either a spoon or in a small glass.
  - Make sure that the entire dose is swallowed.
  - Thoroughly wash and dry your hands before and after preparation of the medicine.

**How to prepare and take the oral suspension using a spoon:**

1. Count the number of dispersible tablets as prescribed by your healthcare professional.
2. Prepare the oral suspension by adding the prescribed number of dispersible tablets to room temperature drinking water in a spoon.
3. Gently stir the liquid for 1 to 3 minutes using the tip of a knife. Drink the resulting white cloudy liquid right away or mix it further with a small portion of apple sauce or yogurt to aid with administration.
4. Add a little more water or apple sauce or yogurt to the spoon and swallow it to make sure all the medicine has been taken.
5. If not taken right away, discard the medicine and prepare a new dose.

Alternatively, instead of drinking water, the oral suspension can be prepared in orange juice, apple juice or skimmed milk.

**How to prepare and take the oral suspension using a small glass:**

1. Count the number of dispersible tablets as prescribed by your healthcare professional.
2. Prepare the oral suspension by adding the prescribed number of dispersible tablets to a small amount (from 10 mL up to maximum 100 mL) of room temperature drinking water in a small glass.
3. Gently stir with a spoon for 1 to 2 minutes. Drink the resulting white cloudy liquid right away.

4. Add a little more water (minimum 5 mL) to the small glass and stir with the same spoon and drink the entire contents of the glass to make sure all the medicine has been taken.
5. If not taken right away, discard the medicine and prepare a new dose.

**Special information for caregivers**

Caregivers are advised to avoid contact with suspensions of OPSUMIT dispersible tablets. Wash hands thoroughly before and after preparation of the suspension.

**Usual Dose:**

Children aged 2 years to less than 18 years of age:

Your healthcare professional will determine the number of tablets of OPSUMIT depending on the body weight of the child.

**Overdose:**

If you think you, or a person you are caring for, have taken too much OPSUMIT, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

**Missed Dose:**

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

**Possible side effects from using OPSUMIT:**

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

Side effects may include:

- Itchy, runny or stuffy nose and congestion (nasopharyngitis);
- Headache;
- Sore throat (pharyngitis);
- Flu (influenza);
- Infected nose, sinuses or throat (upper respiratory tract infection);
- Inflamed stomach or gut (gastroenteritis)
- Increased or abnormal menstrual bleeding.

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	
<b>VERY COMMON</b>			
<b>Anemia</b> (decreased number of red blood cells): fatigue, loss of energy, irregular heartbeats, pale complexion, shortness of breath, weakness	✓		
<b>Bronchitis</b> (irritation of the airways): coughing, mucus production, fatigue, shortness of breath, slight fever and chills, chest discomfort	✓		
<b>Edema:</b> unusual swelling of the arms, hands, legs, feet and ankles, face or airway passages	✓		
<b>COMMON</b>			
<b>Hypotension</b> (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up)	✓		
<b>Urinary tract infection</b> (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	✓		
<b>RARE</b>			
<b>Liver problems:</b> yellowing of your skin and eyes (jaundice), right upper stomach area pain or swelling, fever, nausea or vomiting, unusual dark urine, unusual tiredness		✓	
<b>UNKNOWN FREQUENCY</b>			

<b>Allergic reaction:</b> 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 ( [canada.ca/drug-device-reporting](https://canada.ca/drug-device-reporting)) 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 at room temperature between 15°C and 30°C in original package.

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 [innovativemedicine.jnj.com/canada](http://innovativemedicine.jnj.com/canada), or by calling 1-800-567-3331 or 1-800-387-8781.

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