

## PART III: CONSUMER INFORMATION

### <sup>PR</sup>OPSUMIT® Macitentan tablets

This leaflet is part III of a three-part "Product Monograph" published when OPSUMIT was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about OPSUMIT. Contact your doctor or pharmacist if you have any questions about the drug.

### ABOUT THIS MEDICATION

#### What the medication is used for:

OPSUMIT is a prescription medicine used to treat people with certain types of pulmonary arterial hypertension (PAH).

#### What it does:

PAH is high blood pressure in the blood vessels that lead blood from the heart to the lungs. OPSUMIT lowers high blood pressure in your lungs and lets your heart pump blood better.

OPSUMIT may lower the chance of your disease getting worse.

OPSUMIT can be taken alone or with some other PAH medications prescribed by your doctor.

#### When it should not be used:

Do not take OPSUMIT if you:

- are allergic (hypersensitive) to macitentan or any of the other ingredients of OPSUMIT (see "What the nonmedicinal ingredients are").
- are pregnant, if you are planning to become pregnant, or if you could become pregnant because you are not using reliable birth control (contraception).
- are breastfeeding. It is not known if OPSUMIT can pass through your milk and harm your baby. Therefore, breastfeeding is not recommended.

#### What the medicinal ingredient is:

macitentan

#### What the nonmedicinal ingredients are:

lactose monohydrate, magnesium stearate, microcrystalline cellulose, polysorbate 80, polyvinyl alcohol, povidone, and sodium starch glycolate Type A, soya lecithin, talc, titanium dioxide, and xanthan gum

#### What dosage forms it comes in:

10 mg tablet

## WARNINGS AND PRECAUTIONS

### Serious Warnings and Precautions

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

**BEFORE you use OPSUMIT talk to your doctor or pharmacist if:**

- You are or are planning on becoming pregnant.
- OPSUMIT can cause serious birth defects if taken during pregnancy.
- 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.

## INTERACTIONS WITH THIS MEDICATION

**Drugs that may interact with OPSUMIT include:**

- Rifampicin, an antibiotic.

## PROPER USE OF THIS MEDICATION

#### Usual dose:

- Take one tablet once daily with or without food.
- 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.
- If you take more than the prescribed dose of OPSUMIT, call your doctor right away.
- 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:

- 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:

- 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.

**Overdose:**

In case of drug overdose, contact a health care practitioner, 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.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

OPSUMIT can cause serious side effects, including:

- Serious birth defects. See “Warnings and Precautions”.
- Low red blood cell levels (anemia).
- Liver problem.

Most common side effects include:

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

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Very Common	Low red blood cell levels (anemia)	✓		
	Irritation of the airways (bronchitis)	✓		
Common	Urinary tract infection	✓		
Known	Allergic reaction (symptoms include swelling in the mouth, tongue, face and throat, itching, rash)			✓
Rare	Yellowing of the skin or eyes (jaundice) or other symptoms that indicate liver damage such as nausea, vomiting, fever, abdominal pain or unusual tiredness		✓	

*This is not a complete list of side effects. For any unexpected effects while taking OPSUMIT, contact your doctor or pharmacist.*

**HOW TO STORE IT**

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

Keep OPSUMIT out of the reach and sight of children.

**REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701E  
Ottawa, Ontario  
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect® Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at: [www.janssen.com/canada](http://www.janssen.com/canada) or by contacting the sponsor, Janssen Inc., at: 1-800-567-3331 or 1-800-387-8781.

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