

It is important that you report immediately to your prescribing doctor pregnancy or any side effects that may occur during treatment with Opsumit.

Treatment centre: \_\_\_\_\_

Name of prescribing doctor: \_\_\_\_\_

Phone number of prescribing doctor: \_\_\_\_\_

The recommended dose of Opsumit is one 10 mg tablet, once a day. Swallow the whole tablet, with a glass of water, do not chew or break the tablet. You can take Opsumit with or without food.

If you forget to take Opsumit, take a dose as soon as you remember, then continue to take your tablets at the usual times. Do not take a double dose to make up for a forgotten tablet.

**For more information on Opsumit, please read carefully the patient information leaflet.**

**If you have any question about your treatment, ask your doctor or pharmacist.**

**For the treatment of pulmonary arterial hypertension**

This card contains important safety information that you need to be aware of when receiving treatment with Opsumit. Carry this card with you at all times and show it to any doctor involved in your medical care.

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**OPSUMIT<sup>®</sup>** 10 mg  
**macitentan**  
film-coated tablets

This card has been reviewed and approved by The Saudi Food and Drug Authority (SFDA).  
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## **Pregnancy**

Opsumit may harm the development of the foetus. Therefore you must not take Opsumit if you are pregnant, and you must also not become pregnant while taking Opsumit. Moreover, if you are suffering from pulmonary arterial hypertension, the occurrence of a pregnancy can severely deteriorate the symptoms of your disease.

## **Contraception**

You need to use a reliable form of birth control (contraception) while you are taking Opsumit. Be sure to discuss any questions you may have with your doctor.

You should have a pregnancy test before initiation of Opsumit and every month during treatment even if you think that you are not pregnant. Like other medicines of this class, Opsumit can induce anemia (a reduced number of red blood cells) and can have effects on the liver. Your doctor will take blood test before you start treatment with Opsumit and during treatment to test:

- **Whether your liver is working properly.**
  - Signs that your liver may not be working properly include:
    - nausea (urge to vomit)
    - vomiting
    - fever (high temperature)
    - pain in your stomach (abdomen)
    - jaundice (yellowing of your skin or the whites of your eyes)
    - dark-coloured urine
    - itching of your skin
    - lethargy or fatigue (unusual tiredness or exhaustion)
    - flu-like syndrome (joint and muscle pain with fever)
- If you notice any of these signs, tell your doctor immediately.**

For full prescribing information, please refer to the datasheet or contact Johnson & Johnson Middle East FZ-LLC (Riyadh)

Address: Prince Muhammed Bin Abdulaziz Rd, Tower B, Level 30, Olaya towers.

Office Tel 00966-11-4339133

Postal address: P O Box 65305 Riyadh 11556, Saudi Arabia

Adverse events reporting guidance:

You can report any problem or adverse event to:

FDA (National Pharmacovigilance center):

Email: [npc.drug@sfda.gov.sa](mailto:npc.drug@sfda.gov.sa)

Telephone: 19999 , Online: <http://ade.sfda.gov.sa>

Or to Janssen:

Email: [GCC-PV2@its.jnj.com](mailto:GCC-PV2@its.jnj.com)

Hotline: 00966540015811