

It is important to contact your prescribing doctor immediately if you become pregnant or experience any side effects 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 tablet whole, 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 time. Do not take a double dose to make up for a forgotten tablet.

For more information on Opsumit, please read the patient information leaflet carefully. If you have any questions about your treatment, ask your doctor or pharmacist.

©2020 Janssen-Cilag Ltd



7074154

For the treatment of pulmonary arterial hypertension

This card contains important safety information 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.

OPSUMIT (10 mg)
macitentan film-coated tablets

CP-360537 | November 2022

EN

Pregnancy

Opsumit may harm unborn babies. Therefore you must not take Opsumit if you are pregnant and you must also not become pregnant while taking Opsumit or soon after stopping **(Up to 1 month)**.

Pregnancy can also lead to severe deterioration in pulmonary arterial hypertension symptoms.

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.

Blood tests for anaemia and liver function

Opsumit can induce anaemia (a reduced number of red blood cells) and can cause liver injury. You will have blood tests before you start treatment and regularly during treatment to check:

- whether you have anaemia
- whether your liver is working properly

Signs that your liver may not be working properly include:

- nausea (feeling sick)
- 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

If you get any side effects, talk to your doctor, nurse or pharmacist. Please report suspected adverse drug reactions (ADRs) to the Health Products Regulatory Authority Website: www.hpra.ie. Alternatively you can call Janssen on +44 1494 567447 or Email : dsafety@its.jnj.com By reporting side effects you can help provide more information on the safety of this medicine. By reporting side effects you can help provide more information on the safety of this medicine.



Electronic Signature Form

Code: CP-360537

Name: Opsumit Risk Management Materials IE - Patient Alert Card

Country: Ireland

Product: Opsumit_IE_PAH°

Distribution Method: Key Account Manager (KAM) Medical Affairs Team

Audience: Healthcare_Professional

Project Owner: Eimear O'Reilly

Document Type: Copy Review Piece

Promotional Content: Non-Promotional Content

I hereby certify that this material is in its final form and that, in my belief, it is in accordance with the requirements of the relevant local regulations and Code of Practice and is a fair and truthful presentation of the facts.

Signatory Approvals

Signatories Approval	Kenneth McDonald EMEA Signatories 16-Mar-2023 13:33:23 GMT+0000
----------------------	---