

Patient Card.

Opsumit® macitentan

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

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

Treatment centre:

Name of prescribing doctor:

Phone number of prescribing doctor:

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

Suspected adverse reactions that may occur during treatment should be reported via adverse drug reactions (ADRs) to Malta Medicines Authority via the ADR Reporting Website:

www.medicinesauthority.gov.mt/adrportal.

For further information regarding this medication please contact local representative:

EJ Busuttil Ltd.

Phone: 2147184 (service is available 24/7)

Email: safety@ejbusuttil.com