

Patient Card

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<p>For the treatment of pulmonary arterial hypertension</p> <p>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.</p> <p>Opsumit® 10 mg macitentan film-coated tablets</p> <p>EN</p>	<p>It is important that you report immediately to your prescribing doctor pregnancy or any side effects that may occur during treatment with Opsumit.</p> <p>Treatment centre: _____</p> <p>Name of prescribing doctor: _____</p> <p>Phone number of prescribing doctor: _____</p>
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<p>Pregnancy</p> <p>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.</p> <p>Contraception</p> <p>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.</p>	<p>You should have a pregnancy test before initiation of Opsumit and every month during treatment even if you think that you are not pregnant.</p> <p>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:</p> <ul style="list-style-type: none">• whether your liver is working properly
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<p>Signs that your liver may not be working properly include:</p> <ul style="list-style-type: none">• 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) <p>If you notice any of these signs, tell your doctor immediately.</p>	
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Call for reporting
Jordan Food and Drug Administration (JFDA)

Email: jpc@jfda.jo
Website: <http://www.jfda.jo/>

Electronic reporting form: <https://primaryreporting.who-umc.org/JO>
Tel: +962-6-5632000
QR Code



Company contact points
Janssen scientific office:
Telephone: +2 21291100 Mobile: +2 01000629760
E-mail: JACEG-PV@its.jnj.com **Adverse events related to Opsumit should be reported to**
Janssen PV department
Email: JACEG-PV@its.jnj.com