

## Opsynvi (macitentan/ tadalafil) Patient Card

For the treatment of pulmonary arterial hypertension

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

**Opsynvi 10 mg/20 mg film-coated tablets**  
**Opsynvi 10 mg/40 mg film-coated tablets**

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

Treatment centre:

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Name of prescribing doctor:

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Phone number of prescribing doctor:

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*This card has been reviewed and approved by The Saudi Food and Drug Authority (SFDA). Version 1. August-2025* *fold here*

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Opsynvi

## Pregnancy

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

## Contraception

Women who can become pregnant should use effective birth control before starting macitentan/tadalafil, while taking the medication, and for 1 month after stopping it to help prevent any harm to the baby. Talk with your healthcare provider or gynecologist (a doctor who specializes in female reproduction) to find out about options for acceptable birth control that you may use to prevent pregnancy during treatment with macitentan/tadalafil .

You should have a pregnancy test before initiation of Opsynvi and every month during treatment even if you think that you are not pregnant.

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Opsynvi can have effects on the liver. Your doctor will take blood test before you start treatment with Opsynvi 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 (right upper quadrant pain)
- 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)
- anorexia (loss of appetite)

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If you notice any of these signs, tell your doctor immediately.

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

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**Opsynvi**<sup>®</sup>  
macitentan/tadalafil  
10 mg/40 mg tablets

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Adverse events reporting guidance:  
SFDA (National Pharmacovigilance center)  
Email: [npc.drug@sfd.gov.sa](mailto:npc.drug@sfd.gov.sa)  
Telephone: 19999  
Online: <http://ade.sfda.gov.sa>

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For full prescribing information, please refer to the datasheet or contact Johnson & Johnson Trading Limited (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

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To report Adverse Events/Product Complaint or any Medical Information Inquiries, please contact us at:  
Email: [GCC-PV2@its.jnj.com](mailto:GCC-PV2@its.jnj.com)  
Hotline: 00966540015811

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