



Important safety reminders for patients taking OPSUMIT® (macitentan) or OPSYNVI® (macitentan and tadalafil)

This card contains important safety information about OPSUMIT® or OPSYNVI®. Read this card carefully before starting your treatment with OPSUMIT® or OPSYNVI®. Carry this card with you at all times. SHOW THIS CARD to any healthcare professionals involved in your care.

Your name: _____

Prescribing doctor: _____

Prescribing doctor's contact number: _____

This card was developed by Johnson & Johnson International (Singapore) Pte. Ltd. as a risk minimization tool for OPSUMIT® and OPSYNVI® and is not intended for promotional use.

Blood tests to be performed during treatment

Regular blood tests for liver function and red blood cell levels is an important part of your treatment.

Some patients taking macitentan were found to have abnormal liver function values (increase in liver enzymes) or anemia (reduction in red blood cells). Because these findings may not cause symptoms you can feel or observe yourself, your doctor will do regular blood tests to assess any changes in your liver function and red blood cell levels.

Blood tests to assess liver function and anemia will be done:

- Prior to treatment initiation
- Repeated during treatment if needed, as decided by your doctor

If you develop abnormal liver function or anemia, your doctor may decide to stop treatment with OPSUMIT® or OPSYNVI®. When your blood test results return to normal, your doctor may decide to restart treatment with OPSUMIT® or OPSYNVI®.

Be aware of the signs and symptoms associated with hepatotoxicity and anemia:

- **Liver problems (hepatotoxicity).** OPSUMIT® or OPSYNVI® can cause liver problems. Tell your doctor if you have any of the following signs of liver problems during treatment with OPSUMIT® or OPSYNVI®:
 - Nausea or vomiting
 - Yellowing of your skin or whites of your eyes
 - Pain in the upper right stomach
 - Dark urine
 - Fever
 - Tiredness
 - Itching
 - Loss of appetite
- **Low red blood cell levels (anemia)** can occur with OPSUMIT® or OPSYNVI® treatment, usually during the first weeks after starting therapy. Signs of anemia:
 - Tiredness
 - Shortness of breath
 - Pale skin

What to do: Your doctor will make sure you continue to have regular blood tests to check for this side effect. Contact your doctor immediately if you experience any of these signs and symptoms.

If you are a female patient of childbearing age, read this section carefully

Do not use OPSUMIT® or OPSYNVI® if:

- You are pregnant, think you may be pregnant, plan to become pregnant, or could become pregnant because you are not using reliable birth control. OPSUMIT® or OPSYNVI® can cause serious birth defects if taken during pregnancy
- You are breastfeeding or plan to breastfeed

Other warnings you should know about:

- OPSUMIT® or OPSYNVI® may harm your unborn baby
- You should not become pregnant while taking OPSUMIT® or OPSYNVI® and for at least 1 month after stopping your treatment
- Females who are able to get pregnant must take a pregnancy test before starting OPSUMIT® or OPSYNVI®
- Your doctor may recommend that you take a pregnancy test every month during your treatment to allow the early detection of pregnancy

Talk with your doctor or gynecologist (a doctor who specializes in female reproduction) to find out about how to prevent pregnancy. Do not have unprotected sex. Tell your doctor right away if you had unprotected sex, missed a menstrual period, think your birth control has failed or suspect that you may be pregnant for any reason.

If you become pregnant, tell your healthcare professional right away. Stop taking OPSUMIT® or OPSYNVI®.

For male patients who plan on fathering a child:

- Speak with your doctor before using OPSUMIT® or OPSYNVI®, as decreases in sperm count have been observed with macitentan, an ingredient of this medication.

Important Safety Information For Healthcare Professionals

This patient is being treated with OPSUMIT® or OPSYNVI®, which contains macitentan and is associated with hepatotoxicity and anemia. Assess the patient for signs and symptoms of hepatotoxicity and anemia, including but not limited to those listed on this card. Please contact the patient's prescribing doctor for further information.

For more information about OPSUMIT® or OPSYNVI®, please scan the QR code for the Singapore Package Insert below.

Johnson & Johnson

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For Healthcare Professionals



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