

PATIENT MEDICATION GUIDE

OPSUMIT® Macitentan tablets

ABOUT THIS MEDICATION

What the medication is used for:

OPSUMIT is a prescription medicine used to treat people with certain types of pulmonary arterial hypertension (PAH).

What it does:

PAH is high blood pressure in the blood vessels that lead blood from the heart to the lungs. OPSUMIT lowers high blood pressure in your lungs and lets your heart pump blood better.

OPSUMIT may lower the chance of your disease getting worse.

OPSUMIT can be taken alone or with some other PAH medications prescribed by your doctor.

When it should not be used:

Do not take OPSUMIT if you:

- are allergic (hypersensitive) to macitentan or any of the other ingredients of OPSUMIT (see "What the nonmedicinal ingredients are").
- are pregnant, if you are planning to become pregnant, or if you could become pregnant because you are not using reliable birth control (contraception).
- are breastfeeding. It is not known if OPSUMIT can pass through your milk and harm your baby. Therefore, breastfeeding is not recommended.

What the medicinal ingredient is:
macitentan

What the nonmedicinal ingredients are:

lactose monohydrate, magnesium stearate, microcrystalline cellulose, polysorbate 80, polyvinyl alcohol, povidone, and sodium starch glycolate Type A, soya lecithin, talc, titanium dioxide, and xanthan gum.

What dosage forms it comes in:

10 mg tablet

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- Serious birth defects.
- Anemia (a reduced number of red blood cells)
- Liver problems

BEFORE you use OPSUMIT talk to your doctor or pharmacist :

- If you are or are planning on becoming pregnant.
- OPSUMIT can cause serious birth defects if taken during pregnancy.
- Do not take OPSUMIT if you are pregnant. Talk to your doctor if you become pregnant while on treatment.
- Females who are able to get pregnant must take a pregnancy test before starting OPSUMIT. Monthly pregnancy tests during treatment with OPSUMIT are recommended to allow the early detection of pregnancy.

- Do not get pregnant while you are taking OPSUMIT. 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 have unprotected sex. Tell your doctor right away if you think your birth control has failed.
- Tell your doctor right away if you miss a menstrual period or think you may be pregnant for any reason.
- Talk to your doctor if you have anaemia or a known liver problem.
- Obtain baseline liver enzyme tests and hemoglobin concentration prior to start of treatment.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including prescription and non-prescription medicines and health supplements. OPSUMIT and other medicines may affect each other causing reduced efficacy or side effects.

Do not start any new medicine until you check with your health care provider.

PROPER USE OF THIS MEDICATION

Usual dose:

- Take one tablet once daily with or without food.
- Take OPSUMIT exactly as your doctor tells you to take it.
- It will be easier to remember to take OPSUMIT if you take it at the same time each day.
- Do not split, crush, or chew OPSUMIT tablets.

- If you take more than the prescribed dose of OPSUMIT, call your doctor right away.
- Do not stop taking OPSUMIT unless your doctor tells you to.

Tests during treatment:

Some patients taking OPSUMIT were found to have abnormal liver function values (increase in liver enzymes) and some patients developed 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 hemoglobin level.

Liver function:

This blood test will be done:

- every month during the first year of treatment or more frequently, if needed.

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

Anemia:

This blood test will be done:

- at one month after treatment start and as decided by doctor thereafter .

If you develop anemia, your doctor may decide to perform further tests to investigate the cause.

Your regular blood tests, both for liver function and anemia, are an important part of your treatment.

Pregnancy:

Monthly pregnancy tests during treatment with Opsumit are recommended to allow the early detection of pregnancy. See 'Warnings and Precautions'.

Missed Dose:

If you miss a dose of OPSUMIT, take your tablet as soon as you remember. Do not take 2 doses at the same time. If it is almost time for your next dose, skip the missed dose. Just take the next dose at your regular time.

Overdose:

If you have taken more tablets than you have been told to take, ask your doctor for advice.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

OPSUMIT can cause serious side effects, including:

- Serious birth defects. See "Warnings and Precautions".
- Low red blood cell levels (anemia).
- Liver problem.

Most common side effects include:

- Stuffy nose (nasopharyngitis)
- Headache
- Sore throat (pharyngitis)
- Flu (influenza)

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN

| Symptom / effect | |
|------------------|--|
| Very Common | Low red blood cell levels (anemia) |
| | Irritation of the airways (bronchitis) |
| Common | Urinary tract infection |
| Known | Allergic reaction (symptoms include swelling in the mouth, tongue, face and throat, itching, rash) |
| Rare | Yellowing of the skin or eyes (jaundice) or other symptoms that indicate liver damage such as nausea, vomiting, fever, abdominal pain or unusual tiredness |

Tell your doctor or pharmacist if you experience any side effects, including any possible side effects not listed in this medication guide.

This is not a complete list of side effects. For any unexpected effects while taking OPSUMIT, contact your doctor or pharmacist.

HOW TO STORE IT

Store OPSUMIT tablets at a temperature not exceeding 30°C.

Keep OPSUMIT out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to your healthcare provider.