

Patient Information Leaflet

Read this package leaflet carefully before you take the medicine.

This medicine has been prescribed for you, and you must not pass it on to others. The medicine could harm them, even if their symptoms are the same as yours.

Keep this leaflet; you may want to read it again later.

Name of Product

Opsumit®

Strength of the medicine

Macitentan 10 mg

Description of Product

White, biconvex, round, film-coated tablet debossed with 10 on both sides

What is in the medicine?

Each film coated tablet of Opsumit contains the active ingredient of 10 mg macitentan, lactose as filling agent and other ingredients.

What is Opsumit and what is it used for?

Opsumit may only be used if prescribed by the doctor.

Opsumit contains the active substance macitentan, which belongs to the group of substances known as endothelin receptor antagonists.

Opsumit is used for the long-term treatment of pulmonary arterial hypertension (PAH), it can be used on its own or with other drugs for PAH. PAH is high blood pressure in the blood vessels (the pulmonary arteries) that carry blood from the heart to the lungs. In people with PAH, these arteries get narrower, so the heart has to work harder to pump blood through them. This causes people to feel tired, dizzy, and short of breath.

Opsumit widens the pulmonary arteries, making it easier for the heart to pump blood through them. This lowers the blood pressure and both relieves the symptoms and improves the course of the disease.

How much and how often should you use Opsumit ?

The recommended dose of Opsumit is one 10 mg tablet, once a day. Swallow the whole tablet, with a glass of water, do not chew or break the tablet. You can take Opsumit with or without food.

The use and safety of Opsumit in children under the age of 12 years has not been established.

When shouldn't you use Opsumit?

You should not take Opsumit if you:

- if you are hypersensitive to macitentan or any of the other ingredients of Opsumit.
- if you are children under the age of 12 years.

- if you are pregnant, if you are planning to become pregnant, or if you could become pregnant because you are not using reliable birth control.
- If before the start of treatment your liver enzymes are greatly elevated

What are the possible side effects of Opsumit?

When Opsumit was taken in controlled clinical studies, the following side effects occurred:

Very common side effects are anaemia (low number of red blood cells) or haemoglobin decreases, headache, bronchitis, nasopharyngitis (inflammation of the nasopharynx).

Oedemas (swelling, especially of the ankles and the feet).

Common side effects are pharyngitis (inflammation of the throat), blocked nose, influenza (flu), urinary tract infection, gastroenteritis, Menstrual disorders (primarily bleeding) and ovarian cyst in women.

Uncommon side effects are hypersensitivity reactions (swelling in the region of the eyes, face, lips, tongue or throat, itching or skin rash).

Please note that, because of undesirable effects, such as headache, this medicine can adversely affect reaction speed, fitness to drive, and the ability to use machines.

If you notice any side effects not mentioned here while taking Opsumit or if any of the mentioned side effects worries you, please tell your doctor or pharmacist.

Can Opsumit be taken during pregnancy or the breastfeeding period?

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Opsumit may harm unborn babies conceived before, during or soon after treatment.

You must not take Opsumit if you are pregnant or plan to get pregnant.

If it is possible you could become pregnant, use a reliable form of birth control (contraception) while you are taking Opsumit. Talk to your doctor who will advise you regarding reliable methods of contraception. The contraception must be continued for 1 month after the end of the Opsumit therapy.

If you become pregnant or think that you may be pregnant while you are taking Opsumit, see your doctor immediately.

If you are a woman who could become pregnant, your doctor will ask you to take a pregnancy test before you start taking Opsumit and regularly while you are taking Opsumit.

Tell your doctor if you are breast-feeding. You are advised to stop breast-feeding if Opsumit is prescribed for you, because it is not known whether this medicine passes into human breast milk.

What other medicine or food should be avoided whilst taking Opsumit?

Concomitant use of Opsumit and Rifampicin (Treatment of infectious disease including tuberculosis) as well as Ketoconazole (treatment of fungal infections) can affect each other

What should you do if you miss a dose?

If you forget to take Opsumit, take a dose as soon as you remember, then continue to take your tablets at the usual times. Do not take a double dose to make up for a forgotten tablet.

How should you keep Opsumit?

Do not store Opsumit film coated tablets above 30°C and keep Opsumit out of reach of children.

Sign & Symptom of over dosages

Macitentan has been administered as a single dose of up to and including 600 mg to healthy subjects. Adverse events of headache, nausea, and vomiting were observed. In view of the mechanism of action, overdose could possibly also lead to hypotension.

What to do when you taken more than the recommended dosage?

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

What else do you need to know?

Do not use Opsumit after the date shown next to "EXP" on the container.

Further information can be obtained from your doctor or pharmacist, who has the detailed prescribing Information.

Name / logo of manufacturer/ importer/ marketing authorization

Manufactured by:

Excella GmbH & Co.KG
Nuernberger Strasse 12
90537 Feucht, Germany

Marketing authorization holder

Janssen - Cilag Thailand
106 Moo 4, Ladkrabang Industrial Estate,
Chalongkrung Road, Lamplatew
Ladkrabang, Bangkok 10520

Under Authority of

Actelion Pharmaceuticals Ltd.
Gewerbstrasse 16, CH-4123 Allschwil, Switzerland

Care that should be taken when taking Opsumit?

Opsumit is a treatment that you will need to keep on taking to control your PAH. Do not stop taking Opsumit unless you have agreed this with your doctor.

Always take Opsumit exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Do not depart from the prescribed dose. If you have the impression that the effect of Opsumit is too strong or too weak, talk to your doctor or pharmacist.

When should you consult your doctor?

If you have anaemia (a reduced number of red blood cells).

Before you start treatment with Opsumit and during treatment your doctor will take blood tests to control the number of blood cells and 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, yellowing of your skin or the whites of your eyes (jaundice), dark-coloured urine, itching of your skin, 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 your disease is not due to a blocked or narrowed artery but is due to a blocked or narrowed vein of the lungs.

If you suffer from renal deficiency.

If you have an HIV infection.

If you respond with an intolerance to certain sugars (eg Lapp lactase deficiency or glucose-galactose malabsorption) tell your doctor before you take this medicine.

Opsumit may have a negative effect on male fertility.

Tell your doctor or pharmacist if you

- have any other diseases,
- have any allergies, or
- are taking or applying any other medicines (including ones which you have bought yourself).

Date of revision of PIL

January 2019