

เอกสารกำกับยาภาษาอังกฤษสำหรับผู้ป่วย

OPSUMIT®

Read this leaflet carefully before you start taking/using the medicine.

This medicine has been personally prescribed for you and you may not share it with anyone else. Even if they have the same disease symptoms as you, the medicine could harm them. Keep this leaflet, you may want to read it again later.

Name of Product

OPSUMIT®

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.

Strength of the medicine

Macitentan 10 mg

What is OPSUMIT and when is it used?

On medical prescription.

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.

When must OPSUMIT not be used?

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

When should you be cautious when taking OPSUMIT?

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.

OPSUMIT may have a negative effect on male fertility.

OPSUMIT should not be given to children under the age of 12 years.

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.

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

Please only take OPSUMIT after consulting your doctor if you know that you are suffering from sugar intolerance.

OPSUMIT contains less than 1 mmol sodium (23 mg) per film-coated tablet, i.e. it is almost "sodium-free".

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!).

Should OPSUMIT be taken during pregnancy or while breastfeeding?

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.

How do you use OPSUMIT?

The recommended dose of OPSUMIT is one 10 mg film-coated tablet, once a day. Swallow the whole film-coated tablet, with a glass of water, do not chew, divide or crush the film-coated tablet. You can take OPSUMIT with or without food.

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

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

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

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.

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.

Do not change the prescribed dose on your own. If you believe that the effect of the medicine is too weak or too strong, talk to your doctor or pharmacist.

What side effects can OPSUMIT have?

When OPSUMIT was taken in controlled clinical studies and after market launch, the following side effects occurred:

Very common (affects more than one in 10 patients treated)

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 (affects 1 to 10 in 100 patients treated)

Pharyngitis (inflammation of the throat), influenza (flu), urinary tract infection, hypotension, blocked nose, gastroenteritis, increased level of liver enzymes in the blood, low number of white blood cells, decreased number of 'platelets' (cells that help blood to clot), menstrual disorders in women (primarily bleeding), ovarian cyst, flushing (redness of the skin).

Uncommon (concerns 1 to 10 in 1000 patients treated)

Hypersensitivity reactions (swelling in the region of the eyes, face, lips, tongue or throat, itching and/or skin rash).

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.

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.

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.

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 take more than the recommended dosage?

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

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.

What else should be considered?

The medicine may be used only until the date indicated on the container with "expiry".

Storage instructions

Do not store above 30°C.

Keep out of reach of children.

Further instructions

Further information may be obtained from your doctor, pharmacist. These people have the detailed prescribing information.

What does OPSUMIT contain?

Active ingredients

Each film-coated tablet of OPSUMIT contains 10 mg macitentan.

Excipients

Tablet core:

Lactose monohydrate, microcrystalline cellulose, sodium starch glycolate (Type A), povidone, magnesium stearate, polysorbate 80.

Film-coat: Polyvinyl alcohol, talc, soya lecithin, xanthan gum, titanium dioxide.

Marketing authorization number

1C 37/61 (N)

Date of authorization

11-MAY-2018

SMP Released: 18-JAN-2024

What packages are available?

OPSUMIT film-coated tablets 10 mg: 30 tablets per pack

Date of revision of the text

22 Feb 2024 (Swiss PIL version MAR 2023)

Manufactured by:

EXCELLA GMBH & CO.KG, FEUCHT, GERMANY

Imported by

Janssen-Cilag Ltd., Bangkok, Thailand

To report Suspected Adverse Reactions, please contact us at aepqcjacth@its.jnj.com

For any product information, please contact us at medinfosea@its.jnj.com

Please see full prescribing information at <https://ndi.fda.moph.go.th>