

OPSUMIT® 10MG FILM-COATED TABLETS

Macitentan (10mg)

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What Opsumit is used for

Opsumit is used for the long-term treatment of pulmonary arterial hypertension (PAH) in adults of WHO Functional Class (FC) II to III; it can be used on its own or with other medicines for PAH. PAH is high blood pressure in the blood vessels that carry blood from the heart to the lungs (the pulmonary arteries).

How Opsumit works

Opsumit contains the active substance macitentan, which belongs to the class of medicines called “endothelin receptor antagonists”.

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, relieves the symptoms and improves the course of the disease.

Before you use Opsumit

- *When you must not take it*

- If you are allergic to macitentan, soya or any of the other ingredients of Opsumit.
- 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

(contraception). See section ‘Things you must do’.

- If you are breastfeeding. See section ‘Things you must do’.
- If you have liver disease or if you have very high levels of liver enzymes in your blood. Talk to your doctor, who will decide whether this medicine is suitable for you.

If any of these apply to you, please tell your doctor.

- *Before you start to use it*

Talk to your doctor or pharmacist before taking Opsumit.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

You will need blood tests, as indicated by your doctor:

Your doctor will take blood test before you start treatment with Opsumit and during treatment to test:

- whether you have anaemia (a reduced number of red blood cells)
- whether your liver is working properly

If you have anaemia (a reduced number of red blood cells), you may have the following signs:

- dizziness
- fatigue/malaise/weakness
- fast heart rate, palpitations
- pallor

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

Signs that your liver may not be working properly include:

- feeling sick (nausea)
- vomiting
- fever
- pain in your stomach (abdomen)
- yellowing of your skin or the whites of your eyes (jaundice)
- dark-coloured urine
- itching of your skin

- unusual tiredness or exhaustion (lethargy or fatigue)
- flu-like syndrome (joint and muscle pain with fever)

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

If you have kidney problems, talk to your doctor before using Opsumit. Macitentan may lead to more reduction of blood pressure and decrease in haemoglobin in patients with kidney problems.

In patients with pulmonary veno-occlusive disease (obstruction of the lung veins), the use of medicines for treatment of PAH, including Opsumit, may lead to pulmonary oedema. If you have signs of pulmonary oedema when using Opsumit, such as a sudden, important increase in breathlessness and low oxygen, tell your doctor immediately. Your doctor may perform additional tests, and will determine what treatment regimen is most suitable for you.

Children and adolescents

Do not give this medicine to children and adolescents below 18 years because Opsumit has not been tested in children.

- *Taking other medicines*

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine. Opsumit can affect other medicines.

If you take Opsumit together with other medicines including those listed below, the effects of Opsumit or the other medicines might be altered. Please talk to your doctor or pharmacist if you are taking any of the following medicines:

- rifampicin, clarithromycin, telithromycin, ciprofloxacin, erythromycin (antibiotics used to treat infections),
- phenytoin (a medicine used to treat seizures),
- carbamazepine (used to treat depression and epilepsy),

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- St. John's Wort (an herbal preparation used to treat depression),
- ritonavir, saquinavir (used to treat HIV infections),
- nefazodone (used to treat depression),
- ketoconazole (except shampoo), fluconazole, itraconazole, miconazole, voriconazole (medicines used against fungal infections)
- amiodarone (to control the heartbeat)
- cyclosporine (used to prevent organ rejection after transplant)
- diltiazem, verapamil (to treat high blood pressure or specific heart problems)

Opsumit with food

If you are taking piperine as a dietary supplement, this may alter how the body responds to some medicinal products, including Opsumit. Please talk to your doctor or pharmacist should this be the case.

How to use Opsumit

Opsumit should only be prescribed by a doctor experienced in the treatment of pulmonary arterial hypertension.

- How much to use

Adults weighing at least 40 kg

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.

Always take Opsumit exactly as your doctor has told you. Check with your doctor if you are not sure.

- When to use take it

You can take Opsumit with or without food. It is best to take the tablet at the same time each day.

- How long to use it

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 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.

- If you forget to use it

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.

- If you use too much (overdose):

If you have taken more tablets than you have been told to take, you may experience headache, nausea, or vomiting. Ask your doctor for advice.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

While you are using it

- Things you must do

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, 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.

- 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 about this.
- Do not take Opsumit if you are pregnant or planning to become pregnant.
- If you become pregnant or think that you may be pregnant while you are taking Opsumit, or shortly after stopping Opsumit (up to 1 month), 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 (once a month) while you are taking Opsumit.

It is not known if Opsumit is transferred to breast milk. Do not breastfeed while you are taking Opsumit. Talk to your doctor about this.

Fertility

If you are a man taking Opsumit, it is possible that this medicine may lower your sperm count. Talk to your doctor if you have any questions or concerns about this.

- Things you must not do:

Do not take Opsumit if you are pregnant or planning to become pregnant.

- Things to be careful of:

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).

Opsumit contains lactose, lecithin from soya and sodium

Opsumit contains a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Opsumit contains lecithin derived from soya. If you are allergic to soya, do not use this medicine (see 'When you must not take it').

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Driving and using machines

Opsumit can cause side effects such as headaches and hypotension, and the symptoms of your condition can also make you less fit to drive or use machines.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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Uncommon serious side effects (may affect up to 1 in 100 people)

- Allergic reactions (swelling around the eyes, face, lips, tongue or throat, itching and/or rash)
- If you notice any of these signs, tell your doctor immediately.

Very common side effects (may affect more than 1 in 10 people)

- Anaemia (low number of red blood cells) or reduced haemoglobin
- Headache
- Bronchitis (inflammation of the airways)
- Nasopharyngitis (inflammation of the throat and nasal passages)
- Oedema (swelling), especially of the ankles and feet

Common side effects (may affect up to 1 in 10 people)

- Pharyngitis (inflammation of the throat)
- Influenza (flu)
- Urinary tract infection (bladder infection)
- Hypotension (low blood pressure)
- Nasal congestion (blocked nose)
- Elevated liver tests
- Leukopenia (decreased white blood cell counts)
- Thrombocytopenia (decreased blood platelet counts)
- Flushing (redness of the skin)
- Increased uterine bleeding

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website www.npra.gov.my [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Opsumit

- Storage

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

Do not use Opsumit after the expiry date which is stated on the carton and blister after “EXP”. The expiry date refers to the last day of that month.

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

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer require. These measures will help to protect the environment.

Product Description

- What it looks like

Opsumit film-coated tablets are 5.5mm, round, biconvex, white to off-white, debossed with “10” on both sides.

Opsumit film coated tablets - Each contains 10mg macitentan: 30 tablets/pack.

Opsumit is available from pharmacies on prescription only.

- Ingredients

- Active Ingredient
10 mg macitentan

- Inactive ingredients

Lactose monohydrate,
Microcrystalline cellulose (E460i),
Sodium starch glycolate Type A,
Povidone, Magnesium stearate (E470b), Polysorbate 80 (E433). Film coat: Polyvinyl alcohol (E1203), Titanium dioxide (E171), Talc (E553b), soya bean lecithin (E322), Xanthan gum (E415)

- MAL Number

MAL20016146ACRZ

Manufacturer

Excella GmbH & Co. KG

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Product Registration Holder

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