OPSUMIT® DISPERSIBLE TABLET

Macitentan 2.5mg

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What OPSUMIT® is used for

OPSUMIT® contains the active substance macitentan, which belongs to the class of medicines called "endothelin receptor antagonists".

OPSUMIT® is used for the long-term treatment of pulmonary arterial hypertension (PAH) in children aged 2 years to less than 18 years with 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). 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.

How OPSUMIT® works

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 use it*

Do not take OPSUMIT®

- if you are allergic to macitentan or any of the other ingredients of this medicine
- 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 'Pregnancy and lactation.
- if you are breastfeeding. See section 'Pregnancy and lactation'.
- 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*

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

Your doctor will take blood before and during treatment with OPSUMIT® 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.

Pregnancy and lactation

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

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OPSUMIT®. Talk to your doctor about this.

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.

Children and adolescents
Do not give this medicine to children below 2 years of age because efficacy and safety have not been established.

- *Taking other medicines*
Tell your doctor or pharmacist if you or the child are taking, have recently taken or might take any other medicine.
OPSUMIT® can affect other medicines.

If you take or give 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),
- 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 supplements
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.

Always take or give this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

- *How much to use*
Your doctor will determine the number of tablets of OPSUMIT® depending on the body weight of the child.

- *When to use it*
- Take or give OPSUMIT® dispersible tablets once a day.
- Take or give them at about the same time every day.
- They can be taken or given with or without food.

Take or give OPSUMIT® dispersible tablets as an oral suspension only

OPSUMIT® dispersible tablets must be dispersed in liquids to form an oral suspension before they can be given to patients. The oral suspension can be prepared in either a spoon or in a small glass. Take care that the entire dose is swallowed. Hands must be thoroughly washed and dried before and after preparation of the medicine.

How to prepare and take or give the oral suspension using a spoon
1. Prepare the oral suspension by adding the prescribed number of dispersible tablets to room temperature drinking water in a spoon.
2. Gently stir the liquid for 1 to 3 minutes using the tip of a knife. Either give the resulting white cloudy liquid to the child right away or mix it further with a small portion of apple sauce or yoghurt to aid with administration.
3. Add a little more water or apple sauce or yogurt to the spoon and have the child swallow it to make sure all the medicine has been taken.
4. If not taken right away, discard the medicine and prepare a new dose.

Alternatively, instead of drinking water, the oral suspension can be prepared in orange juice, apple juice or skimmed milk.

How to prepare and take or give the oral suspension using a small glass
1. Prepare the oral suspension by adding the prescribed number of dispersible tablets to a small amount (maximum 100 mL) of room temperature drinking water in a small glass.
2. Gently stir with a spoon for 1 to 2 minutes. Have the child drink the resulting white cloudy liquid right away.
3. Add a little more water to the small glass and stir with the same spoon and have the child drink the entire contents of the glass to make sure all the medicine has been taken.
4. If not taken right away, discard the medicine and prepare a new dose.

Special information for caregivers

Caregivers are advised to avoid contact with suspensions of OPSUMIT® dispersible tablets. Wash hands thoroughly before and after preparation of the suspension.

- *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 or giving OPSUMIT® unless you have agreed this with your doctor.

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- *If you forget to use it*

If you forget to take or give OPSUMIT®, take or give a dose as soon as you remember, then continue to take or give the tablets at the usual times. Do not take or give a double dose to make up for a forgotten tablets.

- *If you use too much (overdose)*

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

While you are using OPSUMIT®

- *Things you must do*

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using OPSUMIT®.

Tell your doctor immediately if you become pregnant while using this medication

- *Things you must not do*

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.

- *Things to be careful of*

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 cycle, drive or use machines.

Side Effects

Like all medicines, OPSUMIT® can cause side effects, although not everybody gets them.

Stop taking OPSUMIT® and tell a doctor straight away if you notice any of the following side effects:
swelling around the eyes, face, lips, tongue or throat, itching and/or rash – you may be having an allergic reaction to the medicine.

Very common (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 (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

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

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

Storage and Disposal of OPSUMIT®

- *Storage*

Keep this medicine 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.
Store in original package to protect from moisture.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

OPSUMIT® 2.5 mg dispersible tablets are white to almost white, round, with a "2.5" on one side and with "Mn" on the other side.

OPSUMIT® is supplied as 2.5 mg dispersible tablets in perforated unit dose blisters (Aluminium/ Aluminium) containing 30 x 1 dispersible tablets.

- *Ingredients*

- Active ingredients

The active substance is macitentan. Each dispersible tablet contains 2.5 mg macitentan.

- Inactive ingredients

The other ingredients are mannitol (E421), isomalt (E953), croscarmellose sodium (E468), magnesium stearate (E470b).

- *MAL number(s)*

MAL XXXXXXXXXX

Manufacturer

Excella GmbH & Co. KG
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Product Registration Holder

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