

## ABBREVIATED PRESCRIBING INFORMATION

### **Opsumit 10 mg film-coated tablets.**

#### **What Opsumit is and what it 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 adults; 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. 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.

#### **Do not take Opsumit:**

if you are allergic to macitentan, soya 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 breastfeeding’. If you are breastfeeding. See section ‘Pregnancy and breastfeeding’. 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.

#### **Warnings and precautions:**

Talk to your doctor or pharmacist before taking Opsumit. 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.

#### **Elderly**

There is limited experience with Opsumit in patients older than 75 years. Opsumit should be used with caution in this age group.

#### **Other medicines and Opsumit**

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 (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), itraconazole, voriconazole (medicines used against fungal infections).

#### **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.

#### **How to take Opsumit**

Opsumit should only be prescribed by a doctor experienced in the treatment of pulmonary arterial hypertension. Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. 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. It is best to take the tablet at the same time each day.

#### **If you take more Opsumit than you should**

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 forget to take Opsumit**

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

#### **Possible side effects**

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

#### **Uncommon 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).

#### **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.

-Always read the full prescribing information.

-Healthcare professionals are asked to report any suspected adverse reactions to the Egyptian pharmacovigilance center (EPVC)

-Ministry of health Opsumit leaflet approval date: 15/10/2018.

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