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Package leaflet: information for the user

Opsumit® 10 mg film-coated tablets

(macitentan)

The name of your medicine is Opsumit 10 mg film-coated tablets but will be referred to as Opsumit throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet
1. What Opsumit is and what it is used for
2. What you need to know before you take Opsumit
3. How to take Opsumit
4. Possible side effects
5. How to store Opsumit
6. Contents of the pack and other information

1. 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 of WHO Functional Class (FC) II to III
- in children under 18 years and body weight of at least 40 kg 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.

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.

2. What you need to know before you take Opsumit

Do not take Opsumit
- if you are allergic to macitentan, soya or any of the other ingredients of this medicine (listed in section 6).
- 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.

<u>You will need blood tests, as indicated by your doctor:</u>
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 below 2 years of age because efficacy and safety have not been established.

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, 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
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.

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.

Driving and using machines
Opsumit can cause side effects such as headaches and hypotension (listed in section 4), and the symptoms of your condition can also make you less fit to drive or use machines.

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 section 2 'Do not take Opsumit').

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

3. 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.

Adults and children aged less than 18 years 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. You can take Opsumit with or without food. It is best to take the tablet at the same time each day.

For children weighing less than 40 kg, Opsumit is available as 2.5 mg dispersible tablets.
Your doctor will advise you on your dosing.

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.

4. Possible side effects

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

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

Side effects in children and adolescents
The side effects listed above may also be seen in children. Additional side effects very commonly seen in children include upper respiratory tract infection (infected nose sinuses, or throat) and gastroenteritis (inflamed stomach and gut). Rhinitis (itchy, runny, or blocked nose) was seen commonly in children.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Opsumit

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.

If this medicine becomes discoloured or shows any other signs of deterioration, please contact your pharmacist who will advise you on what to do.

Do not store above 30°C.

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

6. Contents of the pack and other information

What Opsumit contains
- The active substance is macitentan. Each tablet contains 10 mg macitentan.
- The other ingredients are lactose monohydrate (see section 2 "Opsumit contains lactose, lecithin from soya and sodium"), microcrystalline cellulose (E460i), povidone, sodium starch glycolate Type A (see section 2 "Opsumit contains lactose, lecithin from soya and sodium"), magnesium stearate, polysorbate 80 (E433), polyvinyl alcohol (E1203), titanium dioxide (E171), talc (E553b), soya bean lecithin (E322) (see section 2 "Opsumit contains lactose, lecithin from soya and sodium") and xanthan gum (E415).

What Opsumit looks like and contents of the pack
Opsumit 10 mg tablets are white to off-white, biconvex, round, film-coated tablets with "10" on both sides.

Opsumit is supplied as 10 mg film-coated tablets in blister packs of 30 tablets.

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