Package leaflet: information for the user

Opsumit 10 mg film-coated tablets
macitentan

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

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.

2. What you need to know before you take Opsumit

Do not take Opsumit:
- if you are allergic to macitentan 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). Please read the information under 'Pregnancy'.
- if you are breastfeeding. Please read the information under '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

Take special care with Opsumit:
If you have anaemia (a reduced number of red blood cells).

<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

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.

Children and adolescents
Do not give this medicine to children below 18 years.

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
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)

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

Pregnancy
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, 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.

Breastfeeding
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.

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

Important information about some of the ingredients of Opsumit
Opsumit tablets contain small amounts of a sugar called lactose. If you have an intolerance to lactose or any other sugars contact your doctor before taking Opsumit.

Opsumit tablets contain lecithin derived from soya. If you are allergic to soya, do not use this medicine (see section 2 'Do not take Opsumit').

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.

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, 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.

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)

Uncommon side effects (may affect up to 1 in 100 people)
- Hypersensitivity reactions (swelling around the eyes, face, lips, tongue or throat, itching and/or rash)

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

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 on the blister after “EXP”. The expiry date refers to the last day of that month.

Do not store above 30 °C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer require. These measures will help to 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 in the tablet are lactose monohydrate, microcrystalline cellulose (E460i), povidone, sodium starch glycolate Type A, magnesium stearate (E572), polysorbate 80 (E433), polyvinyl alcohol (E1203), titanium dioxide (E171), talc (E553b), soya lecithin (E322), 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 one side.

Opsumit is supplied as 10 mg film-coated tablets in blister packs of 15 or 30 tablets, or in bottles of 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Actelion Registration Ltd
Chiswick Tower 13th Floor
389 Chiswick High Road
London W4 4AL
United Kingdom
Tel: +44 20 8987 3320

Manufacturer
Actelion Manufacturing GmbH
Emil-Barell-Strasse 7
79639 Grenzach-Wyhlen
Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien
Actelion Pharmaceuticals Belgium N.V.
Tél/Tel: +32-(0)15 284 777

България
Аквахим АД
Тел.: +359 2 807 50 00

Česká republika
Actelion Pharmaceuticals CZ, s.r.o.
Tel: +420 221 968 006

Danmark
Actelion Danmark,
Filial af Actelion Pharmaceuticals Sverige AB, Sverige
Tlf: +45 3694 45 95

Deutschland
Actelion Pharmaceuticals Deutschland GmbH
Tel: +49 761 45 64 0

Lietuva
UAB ALGOL PHARMA
Tel: +370 37 40 86 81

Luxembourg/Luxemburg
Actelion Pharmaceuticals Belgium N.V.
Tél/Tel: +32-(0)15 284 777

Magyarország
Actelion Pharmaceuticals Hungaria Kft.
Tel: +36 1 413 3270

Malta
Actelion Pharmaceuticals UK Ltd
Tel: +44 208 987 3333

Nederland
Actelion Pharmaceuticals Nederland B.V.
Tel: +31 (0)348 435950

Eesti
Algol Pharma OÜ
Tel: +372 605 6014

Ελλάδα
Actelion Pharmaceuticals Ελλάς A.E.
Τηλ: +30 210 675 25 00

España
Actelion Pharmaceuticals España S.L.
Tel: +34 93 366 4399

France
Actelion Pharmaceuticals France SAS
Tél: +33 (0)1 58 62 32 32

Hrvatska
Medis Adria d.o.o.
Tel: +385 (0) 1 2303 446

Ireland
Actelion Pharmaceuticals UK Ltd
Tel: +44 208 987 3333

Ísland
Actelion Pharmaceuticals Sverige AB
Sími: +46 (0)8 544 982 50

Italia
Actelion Pharmaceuticals Italia S.r.l.
Tel: +39 0542 64 87 40

Κύπρος
Actelion Pharmaceuticals Ελλάς A.E.
Τηλ: +30 210 675 25 00

Latvija
Algol Pharma SIA
Tel: +371 67 61 9365

Norge
Actelion Pharmaceuticals Sverige AB,
Filial Norge
Tlf: +47 22480370

Österreich
Actelion Pharmaceuticals Austria GmbH
Tel: +43 1 505 4527

Polska
Actelion Pharma Polska Sp. z o.o.
Tel: +48 (22) 262 31 00

Portugal
Actelion Pharmaceuticals Portugal Lda.
Tel: +351 21 358 6120

România
Geneva Romfarm International SRL
Tel: + 40 (021) 231 3561

Slovenija
Medis d.o.o.
Tel: +386-(0)1 589 69 00

Slovenská republika
Actelion Pharmaceuticals SK, s.r.o.
Tel: +420 221 968 006

Suomi/Finland
Actelion Pharmaceuticals Sverige AB,
Filial Finland
Puh/Tel: +358 9 2510 7720

Sverige
Actelion Pharmaceuticals Sverige AB
Tel: +46 8 544 982 50

United Kingdom
Actelion Pharmaceuticals UK Ltd
Tel: +44 208 987 3333

This leaflet was last revised in January 2017

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.