PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 4

OPSUMIT 10 mg

Film coated tablet

Macitentan

37 mg lactose as monohydrate

Contains soya lecithin

Read all of this leaflet carefully before you are given OPSUMIT

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse or other health care provider
- OPSUMIT has been prescribed for you personally and you should not share your medicine with other people. It may harm them even if their symptoms are the same as yours.

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 treatment of pulmonary arterial hypertension (PAH) to delay progression of PAH in adults; it can be used on its own or with other approved 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 hypersensitive (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 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

OPSUMIT can affect other medicines.

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional 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),
- riociguat (used to treat pulmonary arterial hypertension)
- rosuvastatin (used to treat high cholesterol)
- ketoconazole (except shampoo), fluconazole, itraconazole, voriconazole (medicines used against fungal infections)

Pregnancy and breastfeeding

OPSUMIT should not be used during pregnancy and lactation

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or healthcare provider 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 your baby while you are taking OPSUMIT. Talk to your doctor about this.

Fertility
For males intending procreation, your doctor will counsel you on the potential effects on fertility and the use of OPSUMIT. OPSUMIT may cause a decrease in sperm count.

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.
It is not always possible to predict to what extent OPSUMIT may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities of until they are aware of the measure to which OPSUMIT affects them.

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 OPSUMIT (see section 2 'Do not take OPSUMIT').

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

3. How to take OPSUMIT

Do not share medicines prescribed for you with any other person

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

Always take OPSUMIT 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.

Your doctor will tell you how long your treatment with OPSUMIT will last. Do not stop treatment early because you need to control your PAH. If you have the impression that the effect of OPSUMIT is too strong or too weak, tell your doctor or pharmacist.

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. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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

OPSUMIT can cause side effects. Not all side effects reported for OPSUMIT are included in this leaflet. Should your general health worsen or if you experience

any untoward effects while taking OPSUMIT, please consult your healthcare provider for advice.

If any of the following happens, stop taking OPSUMIT and tell your doctor immediately or go to the casualty department at your nearest hospital

- Allergic reactions (swelling around the eyes, face, lips, tongue or throat, itching and/or rash)

Frequent side effects:

- 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
- 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)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of OPSUMIT.

5. How to store OPSUMIT

Store all medicines out of 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.

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 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 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 (E572), 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.

HOLDER OF CERTIFICATE OF REGISTRATION

JANSSEN PHARMACEUTICA (PTY) LTD

(Reg.No. 1980/011122/07)

2 Medical Road, Halfway House,

Midrand 1685, South Africa

MedInfoZA@its.jnj.com

This leaflet was last revised in

06 February 2025

Registration/Application number(s)

49/7.1.3/0271

Access to the corresponding Professional Information

Included in the carton, accompanying this patient information leaflet.