

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using OPSUMIT?

OPSUMIT contains the active ingredient macitentan. OPSUMIT is used to treat pulmonary arterial hypertension (PAH). It can be used on its own or with other drugs to treat PAH.

For more information, see Section [1. Why am I using OPSUMIT?](#) in the full CMI.

2. What should I know before I use OPSUMIT?

Do not use if you have ever had an allergic reaction to macitentan, soya or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. Women of childbearing potential must use reliable birth control (contraception).

For more information, see Section [2. What should I know before I use OPSUMIT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with OPSUMIT and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use OPSUMIT?

For adults, the recommended dose of OPSUMIT is one 10 mg film-coated tablet, once a day with or without food.

For children over 2 years of age, the dose of OPSUMIT dispersible tablets is based on the child's body weight. Children weighing 40 kg or more may use a 10 mg film-coated tablet as a replacement.

More instructions can be found in Section [4. How do I use OPSUMIT?](#) in the full CMI.

5. What should I know while using OPSUMIT?

Things you should do	- Remind any doctor, dentist or pharmacist you visit that you are using OPSUMIT. - Women of childbearing potential must use at least two reliable forms of birth control (contraception) while taking OPSUMIT and for 3 months after you stop taking it. - Tell your doctor immediately if you notice any of the following: become pregnant or trying to become pregnant, have signs of pulmonary oedema, such as a sudden, important increase in breathlessness and low oxygen.
Things you should not do	- Do not stop taking this medicine unless your doctor tells you to. - Do not breast feed while you are taking OPSUMIT.
Driving or using machines	Be careful before you drive or use any machines or tools until you know how OPSUMIT affects you.
Looking after your medicine	- Keep tablets in the original pack, in a cool, dry place where the temperature stays below 30°C. - Keep out of reach of children.

For more information, see Section [5. What should I know while using OPSUMIT?](#) in the full CMI.

6. Are there any side effects?

The common but less serious side effects you may experience include low number of red blood cells (anaemia), swelling caused by fluid buildup in the body, infection of nose or throat. The serious side effects that require medical attention include severe allergic reaction.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine is subject to additional monitoring due to approval of an extension of indications. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

WARNING: OPSUMIT may cause birth defects (harm to unborn babies). Do not take OPSUMIT if you are pregnant or plan to become pregnant.

OPSUMIT®

Active ingredient(s): macitentan (ma-SEE-ten-tan)

Consumer Medicine Information (CMI)

This leaflet provides important information about using OPSUMIT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using OPSUMIT.**

Where to find information in this leaflet:

1. [Why am I using OPSUMIT?](#)
2. [What should I know before I use OPSUMIT?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use OPSUMIT?](#)
5. [What should I know while using OPSUMIT?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using OPSUMIT?

OPSUMIT contains the active ingredient macitentan.

OPSUMIT belongs to a group of medicines called endothelin receptor antagonists (ERA).

OPSUMIT is used to treat pulmonary arterial hypertension (PAH). It can be used on its own or with other drugs to treat PAH.

PAH is high blood pressure in the blood vessels (the pulmonary arteries) that carry blood from the heart to the lungs. 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 should I know before I use OPSUMIT?

Warnings

Do not use OPSUMIT if:

- you are allergic to macitentan, soya or any of the other ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following:

wheezing, swelling of the lips/mouth, difficulty in breathing, hay fever, lumpy rash (hives) or fainting.

- 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).
- you have serious liver disease or very high levels of liver enzymes in your blood.

Check with your doctor if you:

- have an intolerance to lactose or any other sugars. OPSUMIT film-coated tablets contain small amounts of a sugar called lactose.
- have anaemia (low number of red blood cells)
- have liver or kidney problems
- have pulmonary veno-occlusive disease (obstruction of the lung veins)
- have low blood pressure
- are 75 years or older

Your doctor will order blood test before you start treatment and also during treatment with OPSUMIT to check if you have anaemia (low number of red blood cells) or if your liver is working properly.

Signs that your liver may not be working properly include:

- nausea (urge to vomit)
- vomiting
- fever (high temperature)
- pain in your stomach
- jaundice (yellowing of your skin or the whites of your eyes)
- dark-coloured urine
- itching of your skin
- lethargy or fatigue (unusual tiredness or exhaustion)
- flu-like syndrome (joint and muscle pain with fever)

If you notice any of these signs, tell your doctor immediately.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take OPSUMIT if you or your partner are pregnant or planning to become pregnant as it may harm unborn babies conceived before, during or soon after treatment.

Do not become pregnant for at least 3 months after stopping OPSUMIT.

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.

If it is possible you could become pregnant, use at least two reliable forms of birth control (contraception) while you are taking OPSUMIT. You must continue to use contraception for at least 3 months after stopping OPSUMIT. Talk to your doctor about this.

If you become pregnant or think that you may be pregnant while you are taking OPSUMIT, or shortly after stopping OPSUMIT (up to three months), see your doctor immediately.

It is not known if OPSUMIT is transferred to breast milk.

Do not breastfeed while you are taking OPSUMIT. Talk to your doctor the best way to feed your baby if you take OPSUMIT.

Male fertility

If you are a male you should avoid exposing your partner to your semen by use of appropriate contraception.

OPSUMIT may lower your sperm count. Talk to your doctor if you have any questions or concerns about this.

Children and adolescents

OPSUMIT should not be used in children under 2 years of age. The safety of OPSUMIT and how effective it is have not been established in this age group.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with OPSUMIT and affect how it works. You must tell your doctor if you are taking:

- rifampicin, clarithromycin, ciprofloxacin, erythromycin (antibiotics used to treat infections)
- ritonavir (a medicine for HIV infections)
- ketoconazole (except shampoo), itraconazole, voriconazole, fluconazole, miconazole (medicines used against fungal infections)
- phenytoin (a medicine used to treat seizures)
- carbamazepine (a medicine used to treat depression and epilepsy)
- amiodarone (medicines to treat irregular heartbeat)

- ciclosporin (medicine used to prevent organ rejection after transplant)
- diltiazem, verapamil (medicine used to treat high blood pressure or specific heart problems)
- St. John's Wort (a herbal medicine used to support healthy mood balance)
- piperine (a herbal dietary supplement)

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect OPSUMIT.

4. How do I use OPSUMIT?

How much to take

Adults

- The recommended dose of OPSUMIT in adults is one 10 mg film-coated tablet, once a day. Follow the instructions provided and take OPSUMIT until your doctor tells you to stop.
- Swallow the whole film-coated tablet, with a glass of water. Do not chew or break the tablet.

Children over 2 years to less than 18 years of age

Your doctor will tell you the number of OPSUMIT dispersible tablets to take or give for children over 2 years of age. This is based on the body weight of the child.

For children less than 18 years weighing 40 kg or more, 10 mg film-coated tablet may be used as a direct replacement for dispersible tablets.

OPSUMIT is given once a day. Follow the instructions provided and take OPSUMIT until your doctor tells you to stop.

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. The oral suspension can be prepared in either a stainless-steel 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 stainless-steel spoon

- Prepare the oral suspension by adding the prescribed number of dispersible tablets to room temperature drinking water in a stainless-steel spoon.
- 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.
- 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.
- 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 or apple juice or skimmed milk.

How to prepare and take or give the oral suspension using a small glass

- Prepare the oral suspension by adding the prescribed number of dispersible tablets to a small amount (from 10 mL to maximum 100 mL) of room temperature drinking water in a small glass.
- Gently stir with a spoon for 1 to 2 minutes. Have the child drink the resulting white cloudy liquid right away.
- Add a little more water (minimum 5 mL) 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.
- 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.

When to take OPSUMIT

- OPSUMIT can be taken with or without food.
- It is best to take the tablet at the same time each day.

If you forget to take or give OPSUMIT

OPSUMIT should be taken or given regularly at the same time each day.

If you forget to take or give a dose of OPSUMIT at the usual time and it is almost time for the next dose, skip the missed dose and take or give the next dose when you are meant to.

Do not take or give a double dose to make up for the missed dose.

If you take or give too much OPSUMIT

If you think that you have taken or given too much OPSUMIT, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (in Australia telephone **13 11 26** and in New Zealand telephone **0800 POISON** or **0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using OPSUMIT?

Things you should do

If it is possible you could become pregnant, use at least two reliable forms of birth control (contraception) while you are taking OPSUMIT. You must continue to use

contraception for at least 3 months after stopping OPSUMIT. Talk to your doctor about this.

Call your doctor straight away if you:

- if you become pregnant or are trying to become pregnant.
- have signs of pulmonary oedema when using OPSUMIT, such as a sudden, important increase in breathlessness and low oxygen. In patients with pulmonary veno-occlusive disease (obstruction of the lung veins), the use of medicines for treatment of PAH, including OPSUMIT, may cause a build-up of fluid in your lungs (pulmonary oedema).

Remind any doctor, dentist or pharmacist you visit that you are using OPSUMIT.

Things you should not do

- Do not stop taking this medicine without talking to your doctor. OPSUMIT is a treatment that you will need to keep on taking to control your PAH.
- Do not breastfeed while you are taking OPSUMIT.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use OPSUMIT to treat any other complaints unless your doctor says to.

Driving or using machines

OPSUMIT may cause headaches in some people.

Be careful before you drive or use any machines or tools until you know how OPSUMIT affects you.

Looking after your medicine

- Store below 30°C. Keep tablets in the original pack.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Allergic reaction: - including skin rash, swelling of the face and hives, itching Gastrointestinal: - diarrhoea - stomach pain - inflammation of stomach and gut that may cause diarrhoea, abdominal pain, vomiting - irritable bowel syndrome (stomach pain and bloating with diarrhoea or constipation) - haemorrhoids General: - oedema (swelling), especially of the ankle, feet or hands - fever Infection: - infection of the nose, sinuses or throat including nasal congestion, blocked sinuses, itchy, runny or blocked nose - flu - irritated or inflamed throat - bronchitis (inflammation of the airways) - respiratory tract infection - increased sensitivity of the airways in the lungs, causing narrowing and difficulty breathing Liver: - increased level of liver enzymes in the blood - gallstones Mental health: - difficulty sleeping - depression Musculoskeletal: - joint and muscle pain - systemic sclerosis (problem with immune system that causes a build-up of scar tissue in the skin and internal organ) - inflamed tissue (cartilage) in the rib cage which may cause chest pain Nervous system: - headache or migraine	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
Skin related: - ulcer or sore on the skin - pruritus (severe itching of the skin) - eczema (itchy skin rash) Vascular: - flushing - hypotension (low blood pressure) Urogenital: - increased or abnormal uterine bleeding - long or heavy menstrual period - cyst in the ovary - enlarged breasts in men - urinary tract infection (bladder infection) Blood related: - anaemia (low number of red blood cells) - thrombocytopenia (low number of platelets (cells that help blood to clot)) - decreased level of hemoglobin or haematocrit in the blood - increased level of urea in the blood - decreased or increased level of potassium in blood Eye related: - conjunctivitis (inflammation of the eye)	

Serious side effects

Serious side effects	What to do
Allergic reaction: severe allergic reaction causing a swollen face, lips, mouth, tongue or throat, which may lead to difficulty swallowing or breathing	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the

Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems or in New Zealand at <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What OPSUMIT contains

Film-coated tablets

Active ingredient (main ingredient)	macitentan
Other ingredients (inactive ingredients)	lactose monohydrate microcrystalline cellulose sodium starch glycollate type A povidone magnesium stearate polysorbate 80 <u>The film-coating contains:</u> OPADRY AMB complete film coating system OY-B-28920 White, ARTG PI No. 4271
Potential allergens	lactose soya bean products

Dispersible tablets

Active ingredient (main ingredient)	macitentan
Other ingredients (inactive ingredients)	croscarmellose sodium isomalt magnesium stearate mannitol

Do not take this medicine if you are allergic to any of these ingredients.

What OPSUMIT looks like

Film-coated tablets

OPSUMIT 10 mg tablets are white to off white, round, biconvex, film-coated tablets with "10" on both sides, supplied in blister packs of 9 or 30 tablets. (AUST R 205624)

Dispersible tablets

2.5 mg - white to almost white, round, immediate-release dispersible tablet, with a "2.5" on one side and with "Mn"

on the other side. It is supplied in blister pack of 30 tablets (AUST R 457898)

Who distributes OPSUMIT?

JANSSEN-CILAG Pty Ltd

1-5 Khartoum Rd

Macquarie Park NSW 2113 Australia

Telephone: 1800 226 334

NZ Office: Auckland New Zealand

Telephone: 0800 800 806

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