

OPSYNVI® 10/40

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.

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

1. Why am I using OPSYNNVI?

OPSYNVI is a single tablet that contains two medicines, macitentan and tadalafil. OPSYNNVI is used for the treatment for pulmonary arterial hypertension in adults.

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

2. What should I know before I use OPSYNNVI?

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

Talk to your doctor if you have any other medical conditions, such as heart problems, liver problems, 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) during and for at least 3 months after you stop taking it.

For more information, see Section 2. What should I know before I use OPSYNVI? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with OPSYNVI and affect how it works. Do not take OPSYNVI if you are currently taking any nitrates or amyl nitrate.

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 OPSYNVI?

The recommended dose is one tablet, once a day. More instructions can be found in Section [4. How do I use OPSYNVI?](#) in the full CMI.

5. What should I know while using OPSYNVI?

Things you should do

- Remind any doctor, dentist or pharmacist

	<p>you visit that you are using OPSYNNVI.</p> <ul style="list-style-type: none"> • If you are about to be started on any new medicine, especially nitrates (medicines used for the treatment of angina ["chest pain"] or other heart condition), remind your doctor or pharmacist • Tell your doctor immediately if you notice any of the following: become pregnant or are trying to become pregnant, have sudden decrease or loss of vision, have sudden decrease or loss of hearing, have signs of pulmonary oedema such as a sudden, important increase in breathlessness and low oxygen
Driving or using machines	<ul style="list-style-type: none"> • OPSYNNVI can cause dizziness and affect your vision. Be careful driving or operating machinery until you know how OPSYNNVI affects you.

Drinking alcohol	<ul style="list-style-type: none">When taking OPSYNVI with large amounts of alcohol, you may experience dizziness.
Looking after your medicine	<ul style="list-style-type: none">Store below 30°C. Store in original package.Keep out of reach of children

For more information, see Section [5. What should I know while using OPSYNVI?](#) 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, headache or migraine, flushing, sweating, nausea, indigestion, back pain, arm or leg pain and muscle pain. The serious side effects that require medical attention include severe allergic reaction, chest pain, increase, fast or uneven heart rate, prolonged and painful erection and sudden decrease or loss of vision.

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.

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

OPSYNNVI® 10/40

Active ingredients: *macitentan and tadalafil*

Consumer Medicine Information (CMI)

This leaflet provides important information about using OPSYNNVI. **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 OPSYNNVI.**

Where to find information in this leaflet:

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

1. Why am I using OPSYNNVI?

OPSYNNVI is a single tablet that contains two medicines, macitentan and tadalafil. Macitentan belongs to the class of medicines called endothelin receptor antagonists (ERA). Tadalafil belongs to the class of medicines called phosphodiesterase type 5 (PDE5) inhibitors. You should only switch to OPSYNNVI, after you have been on stable doses of macitentan and tadalafil as separate tablets, as instructed by your doctor.

OPSYNNVI is used for the treatment of pulmonary arterial hypertension (PAH) in adults. 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.

OPSYNNVI widens the pulmonary arteries, making it easier for the heart to pump blood through them. This lowers the blood pressure in the blood vessels that carry blood from the heart to the lungs (pulmonary arteries) and may improve some of your symptoms.

2. What should I know before I use OPSYNNVI?

Warnings

Do not use OPSYNNVI if:

- you are allergic to macitentan, tadalafil or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are pregnant, 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'.
- You have a serious liver problems or if you have very high levels of liver enzymes in your blood.
- you are taking any form of nitrates such as amyl nitrite, used in the treatment of angina ("chest pain"). Tadalafil has been shown to increase the effects of these medicines. If you are taking any form of nitrate or are unsure, tell your doctor.
- you have ever had loss of vision – a condition described as "stroke of the eye" (non-arteritic anterior ischemic optic neuropathy - NAION).
- you have had a heart attack in the last 3 months.
- you have severe low blood pressure.
- you have heart problems such as angina, arrhythmias (changes in rhythm or rate of the heartbeat),

uncontrolled high blood pressure, or a stroke in the last 6 months.

- you are taking guanylate cyclase stimulators such as riociguat to treat pulmonary arterial hypertension (i.e., high blood pressure in the arteries of the lungs) or chronic thromboembolic pulmonary hypertension (i.e., high blood pressure in the arteries of the lungs secondary to blood clots that could block blood flow). PDE5 inhibitors, such as tadalafil, have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure, tell your doctor.

Check with your doctor if you:

- have any of the following medical conditions:
 - pulmonary veno-occlusive disease (obstruction of the lung veins)
 - heart problems other than your pulmonary hypertension
 - problems with your blood pressure
 - blood vessel problems
 - any hereditary eye disease
 - an abnormality of red blood cells (sickle cell anaemia)
 - cancer of the bone marrow (multiple myeloma)
 - cancer of the blood cells (leukaemia)
 - any deformation of your penis, or unwanted or persistent erections lasting more than 4 hours
 - liver or kidney problems
- have an intolerance to lactose or some sugars. OPSYNVI contains lactose.

- take any medicines for any other condition.

You will need blood tests, as indicated by your doctor. Your doctor will order some blood tests before you start treatment with OPSYNVI 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

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
- 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 OPSYNVI if you are pregnant or planning to become pregnant as it may harm unborn babies conceived before, during or soon after treatment.

You must not become pregnant for at least 3 months after stopping OPSYNVI.

If you are a woman who could become pregnant, your doctor will ask you to take a pregnancy test before you start taking OPSYNVI and regularly (once a month) while you are taking OPSYNVI.

If it is possible you could become pregnant, use at least two reliable forms of birth control (contraception) while you are taking OPSYNVI. 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 OPSYNVI, or shortly after stopping OPSYNVI (up to three month), see your doctor immediately.

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

Do not breastfeed while you are taking OPSYNVI.

Talk to your doctor the best way to feed your baby if you take OPSYNVI.

Male fertility

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

OPSYNVI may lower sperm count in men. Tell your doctor if being able to have children is important to you.

Children and adolescents

- Do not give OPSYNVI to children or young people below 18 years of age because it has not been tested in children.

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.

Please talk to your doctor or pharmacist if you are taking any of the following medicines:

- rifampicin, clarithromycin, 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 to support healthy mood balance),
- ritonavir (used to treat HIV infections),
- ketoconazole (except shampoo), fluconazole, itraconazole, miconazole, voriconazole (medicines used against fungal infections),
- amiodarone (to control the heartbeat),
- ciclosporin (used to prevent organ rejection after transplant),
- piperine (a herbal preparation),
- nitrates, medicines such as glyceryl trinitrate, used to treat angina (chest pain) and other heart conditions,
- guanylate cyclase stimulators such as riociguat (see additional information under Section [2. What should I know before I use OPSYNNVI?](#)),
- bosentan, sildenafil (other treatments for pulmonary arterial hypertension),
- alpha blockers used to treat high blood pressure or prostate problems,
- diltiazem, verapamil (to treat high blood pressure or specific heart problems),
- medicines used to treat high blood pressure,
- tablets for erectile dysfunction (PDE5 inhibitors),
- grapefruit juice,
- large amount of alcohol.

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

4. How do I use OPSYNNVI?

How much to take

- The recommended dose of OPSYNNVI is one tablet, once a day.

Follow the instructions provided and use OPSYNNVI until your doctor tells you to stop.

When to take OPSYNNVI

- You can take OPSYNNVI with or without food.
- Take the tablet at the same time each day.

How to take OPSYNNVI

- Swallow the whole tablet, with a glass of water. Do not chew or break the tablet.

If you forget to use OPSYNNVI

OPSYNNVI should be used regularly at the same time each day. If you miss your dose at the usual time, 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 the dose you missed.

If you use too much OPSYNNVI

If you think that you have used too much OPSYNNVI, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre **(by calling 13 11 26)**, 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 OPSYNNVI?

Things you should do

Call your doctor straight away if you:

- become pregnant or are trying to become pregnant.
- have signs of pulmonary oedema when using OPSYNNVI, 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 OPSYNNVI, may cause a build-up of fluid in your lungs (pulmonary oedema).

- have sudden decrease or loss of vision in one or both eyes.
- have sudden decrease or loss of hearing or hearing problems such as ringing in the ears, dizziness.
- are about to be started on any new medicine, especially nitrates (medicines used for the treatment of angina ["chest pain"] or other heart condition), remind your doctor and pharmacist who treat you that you are taking OPSYNNVI.
- have not used your medicine exactly as prescribed.

Things you should not do

- Do not stop using this medicine suddenly, unless you have agreed this with your doctor. OPSYNNVI is a treatment that you will need to keep on taking to control your PAH.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how OPSYNNVI affect you.

OPSYNNVI may cause dizziness and affects your vision.

Drinking alcohol

Tell your doctor if you drink alcohol.

When taking OPSYNNVI with large amount of alcohol, you may experience dizziness.

Looking after your medicine

- Store below 30°C.
- Keep your tablets in the original pack until it is time to take them.

Follow the instructions in the carton on how to take care of your medicine properly.

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
<p>Allergic reaction:</p> <ul style="list-style-type: none">• including skin rash, swelling of the face and hives, itching <p>Gastrointestinal:</p> <ul style="list-style-type: none">• indigestion• nausea• vomiting• stomach discomfort or pain• heartburn• diarrhoea• inflammation of stomach and gut that may cause diarrhoea, abdominal pain, vomiting• irritable bowel syndrome (stomach pain and bloating with diarrhoea or constipation)• haemorrhoids <p>Liver:</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • increased level of liver enzymes in the blood • gallstones <p>Nervous system:</p> <ul style="list-style-type: none"> • headache or migraine • dizziness • fainting <p>Musculoskeletal:</p> <ul style="list-style-type: none"> • back pain • muscle pain • arm or leg pain • joint 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 <p>Skin related:</p> <ul style="list-style-type: none"> • sweating • ulcer or sore on the skin <p>Vascular:</p>	

Less serious side effects	What to do
<ul style="list-style-type: none"> • facial flushing • redness of the skin • bleeding nose • low blood pressure <p>Infection:</p> <ul style="list-style-type: none"> • infection of the nose, sinuses or throat including nasal congestion, blocked sinuses, itchy, runny or blocked nose • flu • irritated or inflamed throat • cough • bronchitis (inflammation of the airways) • respiratory tract infection • increased sensitivity of the airways in the lungs, causing narrowing and difficulty breathing <p>Eye related:</p> <ul style="list-style-type: none"> • red eyes, eye pain, swelling of • eyelids • blurred vision 	

Less serious side effects	What to do
<ul style="list-style-type: none"> • conjunctivitis (inflammation of the eye) <p>General:</p> <ul style="list-style-type: none"> • swelling caused by fluid buildup in the body • face swelling • fever <p>Blood related:</p> <ul style="list-style-type: none"> • thrombocytopenia (low number of platelets (cells that help blood to clot)) • decreased level of hemoglobin or haematocrit in the blood • anaemia (low number of red blood cells) • increased level of urea in the blood • decreased or increased level of potassium in blood <p>Mental health:</p> <ul style="list-style-type: none"> • difficulty sleeping • depression <p>Urogenital:</p>	

Less serious side effects	What to do
<ul style="list-style-type: none"> • increased or abnormal uterine bleeding • long or heavy menstrual period • cyst in the ovary • enlarged breasts in men • urinary tract infection 	

Serious side effects

Serious side effects	What to do
<p>Allergic reaction</p> <ul style="list-style-type: none"> • severe allergic reaction causing a swollen face, lips, mouth, tongue or throat, which may lead to difficulty swallowing or breathing <p>Heart related:</p> <ul style="list-style-type: none"> • chest pain • increased or fast heart beat 	<p>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.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • heartbeats feels fast or uneven • heart failure <p>Urogenital:</p> <ul style="list-style-type: none"> • prolonged and painful erection • erection that lasts longer than usual <p>Eye related:</p> <ul style="list-style-type: none"> • decrease or loss of vision <p>Ear related:</p> <ul style="list-style-type: none"> • sudden decrease or loss of hearing* <p>Nervous system:</p> <ul style="list-style-type: none"> • seizures* 	

*Sudden loss or decrease in hearing and seizures have been reported in people taking tadalafil. It is not possible to determine whether these events are related directly to OPSYNVI, to other diseases or medications, to other factors, or to a combination of factors.

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. 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 OPSYNNVI contains

Active ingredient (main ingredient)	macitentan tadalafil
Other ingredients (inactive ingredients)	Tablet core Hydroxypropyl methylcellulose Lactose monohydrate

	<p>Magnesium stearate</p> <p>Microcrystalline cellulose</p> <p>Polysorbate 80</p> <p>Povidone</p> <p>Sodium starch glycollate</p> <p>Sodium lauryl sulfate</p> <p>Film coating</p> <p>Opadry II Complete Film Coating System 30K580008 White, ARTG PI No. 146235</p>
Potential allergens	Lactose monohydrate

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

What OPSYNNVI looks like

OPSYNNVI 10 mg/40 mg is a white to almost-white, oblong, film-coated tablet debossed with “1040” on one side and “MT” on the other side. It is supplied in blister pack containing 30 tablets (AUST R 420130).

Who distributes OPSYNNVI

Janssen-Cilag Pty Ltd

17 Khartoum Road Macquarie Park NSW 2113 Australia

Telephone: 1800 226 334

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