

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.

1. Why am I using VENTAVIS?

VENTAVIS contains the active ingredient iloprost (as trometamol). VENTAVIS is used to treat:

- moderate or severe stages of pulmonary hypertension, caused by some defect of the vessel walls, connective tissue disease or other medications
- moderate and severe cases of secondary pulmonary hypertension that may have been caused by blood clots in the lungs, where surgery is not possible

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

2. What should I know before I use VENTAVIS?

Do not use VENTAVIS if you have certain conditions affecting the heart, if you are at an increased risk of bleeding, have or had a stroke recently or if you have ever had an allergic reaction to VENTAVIS 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.

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

3. What if I am taking other medicines?

Some medicines may interfere with VENTAVIS and affect how it works. The most common medications that affect how VENTAVIS works are medicines for the heart or to lower blood pressure and medicines that thin the blood.

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 VENTAVIS?

- VENTAVIS is taken as inhalation therapy using a special device (a nebuliser).
- The usual dose per inhalation and frequency depends on your individual condition and will be worked out by your doctor.

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

5. What should I know while using VENTAVIS?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using VENTAVIS.• If you become pregnant while taking this medicine, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not take VENTAVIS to treat any other complaints unless your doctor tells you to.• Do not give VENTAVIS to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or operate any tools or machines if you sense low blood pressure or dizziness occurring
Looking after your medicine	<ul style="list-style-type: none">• Keep VENTAVIS in a cool dry place where the temperature stays below 30°C.

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

6. Are there any side effects?

Common side effects: nose bleeds, headache, flushing, chest pain, cough, nausea, jaw pain, leg swelling, fast or irregular heartbeat, signs of low blood pressure, e.g. dizziness, pain when swallowing, mouth and tongue irritation, diarrhoea, vomiting, rash and back pain.

Serious side effects: signs of allergic reaction, e.g. shortness of breath, wheezing.

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.

VENTAVIS[®] (VEN·ta·vis)

Active ingredient: *iloprost* (as trometamol)

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using VENTAVIS?

VENTAVIS contains the active ingredient **iloprost (as trometamol)**. VENTAVIS is a synthetic prostacyclin analogue. It works by widening blood vessels, allowing more blood to reach the lungs and receive oxygen. This widening results in a decreased work load on the heart, which in turn allows the heart to function more effectively, leading to an improved supply of oxygen to the body and reduced strain on the heart.

VENTAVIS is used to treat:

- Moderate or severe stages of pulmonary hypertension, caused by some defect of the vessel walls, connective tissue disease or other medications
- Moderate and severe cases of secondary pulmonary hypertension that may have been caused by blood clots in the lungs, where surgery is not possible

Pulmonary hypertension is a condition where blood pressure is too high in the vessels which transport blood from the heart to the lungs.

2. What should I know before I use VENTAVIS?

Warnings

Do not use VENTAVIS if:

- you are allergic to iloprost, 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 have increased risk of bleeding (for example active stomach ulcers, injuries, haemorrhaging or other bleeding)

- you have severe coronary heart disease or unstable angina (chest pain), heart attack within the last six months
- you have heart failure, severe irregular heart rate, suspected fluid build-up in the lungs
- you have had a stroke or other interruption of blood supply to the brain within the last 3 months
- you have pulmonary hypertension due to the blockage of the veins
- you have congenital or acquired valvular defects with heart function which are not related to your disease

Check with your doctor if you:

- have any other medical conditions, such as:
 - heart failure
 - low blood pressure
 - lung infections or other lung disease including Chronic Obstructive Pulmonary Disease (COPD) and severe asthma
 - liver function problems, or problems with your kidneys that require dialysis
- take any medicines for any other condition

Pulmonary hypertension

- If you have a history of fainting in association with pulmonary hypertension; you should avoid any unusual straining, for example during exercise.
- If fainting occurs when you get out of bed, it may be helpful to take the first dose of the day while you are still in bed; if fainting gets worse, tell your doctor.

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

Check with your doctor if you are pregnant or intend to become pregnant.

If you suffer from pulmonary hypertension, avoid getting pregnant as pregnancy may lead to a worsening of your condition and may even endanger your life.

If there is the possibility that you may become pregnant, use reliable contraception from the time you start treatment and during treatment.

Tell your doctor straight away if you are pregnant, or think you might be pregnant.

The medicine should only be used during pregnancy if your doctor decides that the potential benefit outweighs the potential risk to the foetus.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not breastfeed if you are taking this medicine. It is not known whether the medicine passes into human milk.

Children under 18 years of age

VENTAVIS is not recommended for use in children under 18 years of age.

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 VENTAVIS and affect how it works. These include:

- Medicines used to treat high blood pressure or heart disease
- Medicines which inhibit blood clotting or platelet aggregation. This includes:
 - Aspirin® or acetylsalicylic acid
 - Warfarin
 - Heparin
 - Clopidogrel
 - NSAIDs, e.g. ibuprofen (Nurofen®), diclofenac (Voltaren®)

These medicines may be affected by VENTAVIS or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

4. How do I use VENTAVIS?

Using VENTAVIS with a nebuliser

- VENTAVIS is taken as inhalation therapy using a special device (a nebuliser).
- During nebulisation sessions a facial mask must not be used. Only a mouthpiece should be used.
- VENTAVIS solution should not come in contact with your skin or eyes.
- Oral ingestion of VENTAVIS solution should be avoided.
- To minimise accidental exposure, it is recommended to use VENTAVIS with nebulisers with a filter or inhalation-triggered systems, and to keep the room well ventilated.
- Your doctor will advise you on the appropriate nebuliser to be used. Any additional instructions from the manufacturer of the nebulising device should also be followed carefully.

How much to use

- The usual dose per inhalation that is right for you depends on your individual condition and will be worked out by your doctor
- In patients with liver problems, severe kidney problems and require dialysis, your doctor may

consider different initial doses and dosing intervals depending on how you tolerate the treatment.

- At the beginning of each inhalation session, a new ampoule of VENTAVIS should be used. Break the ampoule and transfer the contents of one ampoule of VENTAVIS completely into the nebuliser immediately before use.
- VENTAVIS solution that is not used in one inhalation session must be discarded.
- Follow the instructions provided and use VENTAVIS until your doctor tells you to stop.

When to use VENTAVIS

- You may have 6 – 9 inhalation sessions per day depending on your individual condition. This is because the effects of VENTAVIS will only last 1-2 hours.
- The duration of one inhalation session is about 4 to 10 minutes.

If you forget to use VENTAVIS

VENTAVIS should be used regularly at the same times each day.

If you miss your dose at the usual time, contact your doctor for instructions on what to do.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose you missed.

If you use too much VENTAVIS

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

Too much VENTAVIS may lead to dizziness, headache, flushing (reddening of the face), nausea (feeling sick), jaw pain or back pain. You may also experience an increase or decrease in blood pressure, slow heartbeat, fast heartbeat, vomiting, diarrhoea or limb pain.

You should immediately:

- phone the Poisons Information Centre
 - (Australia: 13 11 26 or New Zealand: 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 VENTAVIS?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using VENTAVIS.
- **If the effect of VENTAVIS seems too strong or too weak, talk to your doctor or pharmacist.**
- Follow the instructions provided and use VENTAVIS until your doctor tells you to stop.

Call your doctor straight away if you:

- Become pregnant while taking this medicine.

Things you should not do

- Do not stop using this medicine suddenly. If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.
- Do not take VENTAVIS to treat any other complaints unless your doctor tells you to.
- Do not give VENTAVIS to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or lower the dosage without checking with your doctor. If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

Driving or using machines

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

Do not drive or operate any tools or machines if you sense low blood pressure or dizziness occurring; the ability to properly drive or operate machines might be seriously affected.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

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 where the temperature stays below 30°C.

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.

If the packaging is damaged, return it to your pharmacist for disposal.

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
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Bleeding-related:

- bleeding (mostly nosebleed or coughing up of blood); **some serious cases of bleeding have been reported**

Respiratory-related:

- increased cough
- chest pain
- throat irritation
- breathlessness
- mouth and tongue irritation (including pain)
- pain when swallowing
- nasal congestion (stuffy nose)

Gastrointestinal-related:

- nausea and vomiting
- diarrhoea

Skin-related:

- rash

Musculoskeletal-related:

- pain in jaw or spasm of the jaw muscles (difficulty in opening the mouth)
- back pain

Blood vessel-related:

- low blood pressure
- fainting is a common symptom of the illness itself, but can also occur under therapy
- widening of blood vessels (this may cause flushing, that is, a reddening of the face)
- swelling, usually in the legs

Nervous system-related:

- dizziness
- headache

Heart-related:

- fast or irregular heartbeat

Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Signs of an allergic reaction, such as: <ul style="list-style-type: none">• difficulty breathing, shortness of breath or wheezing• swelling of the face, lips, tongue or other parts of the body• rash, itching or hives on the skin	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.
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PO Box 2825
Shortland Street
Auckland 1140
New Zealand

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.

See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.

See MEDSAFE website (www.medsafe.govt.nz) for latest New Zealand Consumer Medicine Information.

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This leaflet was prepared in June 2024.

7. Product details

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

What VENTAVIS contains

Active ingredient (main ingredient)	20 µg iloprost (as trometamol) per 2 mL solution
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• trometamol• 96% ethanol• sodium chloride• hydrochloric acid• water for injections

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

What VENTAVIS looks like

VENTAVIS comes as a (liquid) solution in a 3-mL glass ampoule and is administered as an aerosol by using a special inhalation device.

Each VENTAVIS ampoule contains 2 mL of solution for one inhalation session. A pack of VENTAVIS contains 6 or 30 ampoules (Aust R 97219).

Not all pack sizes may be marketed.

Who distributes VENTAVIS

Bayer Australia Ltd
ABN 22 000 138 714
875 Pacific Highway
Pymble NSW 2073

Bayer New Zealand Limited