

VASODRINE

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 taking VASODRINE?

VASODRINE contains the active ingredient midodrine hydrochloride. VASODRINE is used to treat severe forms of low blood pressure in adults when other treatments are proven unsatisfactory.

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

2. What should I know before I take VASODRINE?

Do not use if you have ever had an allergic reaction to VASODRINE 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 take VASODRINE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VASODRINE 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 take VASODRINE?

- Your doctor will advise the correct dose for you.
- Swallow the tablets whole with a full glass of water. The tablets may be taken with food.
- The last daily dose should be taken at least 4 hours before your bedtime.

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

5. What should I know while taking VASODRINE?

Things you should do	<ul style="list-style-type: none">• Tell any doctor, dentist or pharmacist you visit that you are taking VASODRINE.• If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.• If you become pregnant while taking this medicine, tell your doctor immediately.• Keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">• Do not take VASODRINE to treat any other complaints unless your doctor tells you to.• Do not stop taking your medicine or change the dosage without checking with your doctor.• Do not give your medicine to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how VASODRINE affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in the original container, in a cool dry place where the temperature stays below 25°C.• Keep VASODRINE where children cannot reach it.

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

6. Are there any side effects?

Common side effects include: goose bumps; headache; nausea (feeling sick); heartburn; flushing; chills; increased tear production; sleep disturbances including difficulty sleeping. Tell your doctor if you have abdominal pain; being sick (vomiting); diarrhoea; tingling and itching of the skin and scalp; urge to urinate, difficulty urinating and/or pain when urinating; inflammation of the lining inside the mouth; restlessness, excitability and irritability; dizziness; anxiety, feelings of confusion; slowed heart rate.

Serious side effects include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin; pounding in the ears; stroke; palpitations, irregular heartbeat; chest pain; blurred vision, visual changes; severe or persistent headache; disorder of the skin or mucous membranes starting with a fever and flu like symptoms and rash.

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.

VASODRINE

Active ingredient: midodrine hydrochloride (*mid-OH-drean HIGH-droe-KLOR-ide*)

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking VASODRINE?

VASODRINE contains the active ingredient **midodrine hydrochloride**. It works by raising your blood pressure. VASODRINE belongs to a group of medicines called adrenergic agents.

VASODRINE is used to treat severe forms of low blood pressure in adults when other treatments are proven unsatisfactory.

2. What should I know before I take VASODRINE?

Warnings

Do not take VASODRINE if you:

- are allergic to midodrine hydrochloride, or any of the ingredients listed at the end of this leaflet.
Some of the symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.
Always check the ingredients to make sure you can use this medicine.
- have high blood pressure
- have a condition called vasovagal hypotension (low blood pressure)
- have a slow pulse
- have certain forms of cardiovascular disease e.g. heart attack, heart failure, blood vessel disease, changes in heart rhythm
- have elevated pressure in the eye (glaucoma) or poor vision because of damage to the eye caused by diabetes
- have an overactive thyroid gland (hyperthyroidism)
- have difficulty passing urine

- have severe kidney disease or inflammation of the kidneys
- have hormonal disorders caused by a rare tumour in the adrenal gland, which sits near the kidney (phaeochromocytoma)
- have prostate problems
- are under 18 years of age. The safety and efficacy of VASODRINE in children has not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

Check with your doctor if you:

- have high blood pressure when you lie down.** If this applies to you then: regular monitoring of your blood pressure will be required when you are lying down and standing up as there may be a risk of your blood pressure rising when you lie down, for example, at night. If your blood pressure rises when you lie down and reducing the dose does not correct this problem, then treatment with this medicine must be stopped. Patients with a history of strokes will need to be monitored. Patients undergoing long term treatment require kidney and blood pressure monitoring.
- have a serious disorder of the nervous system** (autonomic nervous system disorders), since taking VASODRINE may lead to a further drop in blood pressure when you stand up. If this occurs, further treatment with VASODRINE should be stopped
- have a disease of the arteries** which leads to circulation problems including pain or cramps in the stomach after eating, or pain or cramps in the legs while walking
- have a disease of the prostate**, as you may find passing urine is difficult when taking VASODRINE.
- have diabetes**
- have any other medical conditions
- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives or dyes.

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. Your doctor may also perform some tests such as checking your kidney function and blood pressure before you start using this medicine. 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.

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

Using this medicine while pregnant or breastfeeding is not recommended.

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 and VASODRINE may interfere with each other. These include:

- vasoconstrictors (medicines that narrow blood vessels) and sympathomimetic agents (medicines that have a stimulating effect on certain parts of the nervous system. These drugs include reserpine and guanethidine).
- tricyclic antidepressants and MAO-inhibitors (medicines used to treat depression)
- hormones for the thyroid (used when the thyroid is not working properly)
- dihydroergotamine (medicine used to treat migraines)
- antihistamines (medicines used to treat allergy such as hay fever)
- decongestants
- some appetite suppressants
- drugs which cause hypertension such as methyldopa
- prazosin (medicines used to treat heart disease)
- corticosteroid preparations such as fludrocortisone acetate (an anti-inflammatory medicine)
- digitalis preparations (medicines used to treat heart disease) or other glycoside preparations
- medicines that may slow down the heart rate
- promethazine (medicine used to treat allergies and help with vomiting)
- quinidine (medicine used to change the way the heart beats)
- antibiotics and antivirals (medicines used to treat infections).

These medicines may be affected by VASODRINE or may affect how well it works. Some may enhance or block the effects of midodrine or affect the heartbeat. Others will require that decrease your salt intake. You may need different amounts of your medicines, or you may need to take different medicines.

If you are taking medicines which directly or indirectly reduce your heart rate, your doctor will closely monitor you while you are taking VASODRINE.

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

4. How do I take VASODRINE?

How much to take

- **Follow all directions given to you by your doctor or pharmacist carefully.** They may differ from the information contained in this leaflet. If you do not understand the instructions, ask your pharmacist for help.
- **Your doctor will decide your dose** and tell you how long you should take this medicine.
- **The usual recommended starting dose is one 2.5 mg tablet three times each day.**

- **This dose may be increased weekly by your doctor up to your maintenance dose.** The dose may be increased to a dose of four 2.5 mg tablets, or two 5 mg tablets (10 mg) three times daily, which is the usual maintenance dose of 30 mg per day.
- The increase may occur over a longer time period in older patients.
- **Swallow the tablets whole with a full glass of water.** The tablets may be taken with food.
- **Continue taking your medicine for as long as your doctor tells you.** This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.
- If you are taking medicines which directly or indirectly reduce your heart rate, your doctor will closely monitor you while you are taking VASODRINE.

When to take VASODRINE

- **VASODRINE should be taken at about the same times each day.** Taking it at the same times each day will have the best effect. It will also help you remember when to take it.
- **Avoid taking this medicine in the late evening.** The last daily dose should be taken at least 4 hours before your bedtime.
- Keep your head elevated when you lie down at night. This reduces the potential risk of rise in your blood pressure.

If you forget to take VASODRINE

VASODRINE should be used regularly at the same times each day. If you miss your dose at the usual time, take your dose as soon as you remember, and continue to take it as you would normally.

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. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much VASODRINE

If you think that you have taken too much VASODRINE, 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.

Symptoms of an overdose may include:

- high blood pressure
- goose bumps and feeling cold
- slow heartbeat
- difficulty passing urine

5. What should I know while taking VASODRINE?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are taking VASODRINE.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking VASODRINE.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked. During treatment with this medicine your blood pressure will be checked from time to time, and if necessary your dose adjusted.

It is important that you immediately report symptoms related to high blood pressure such as elevated heart rate, headache and blurred vision. Your doctor will then decide whether to adjust dosage or discontinue your treatment with VASODRINE.

Things you should not do

- Do not take VASODRINE to treat any other complaints unless your doctor tells you to.
- Do not give your medicine 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.

Driving or using machines

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

VASODRINE may cause dizziness in some people

Looking after your medicine

- Keep your medicine in the original container. If you take it out of its original container it may not keep well.
- Keep your medicine below 25°C.

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.

When to discard your medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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
<ul style="list-style-type: none"> • goose bumps • headache • nausea (feeling sick) • heartburn • flushing • chills • increased tear production • sleep disturbances including difficulty sleeping • abdominal pain • being sick (vomiting) • diarrhoea • tingling and itching of the skin and scalp • urge to urinate, difficulty urinating and/or pain when urinating • inflammation of the lining inside the mouth • restlessness, excitability and irritability • dizziness • slowed heart rate • anxiety, feelings of confusion 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • shortness of breath • wheezing or difficulty breathing • swelling of the face, lips, tongue or other parts of the body • rash, itching or hives on the skin • pounding in the ears • stroke • palpitations, irregular heartbeat • chest pain • blurred vision, visual changes • severe or persistent headache • disorder of the skin or mucous membranes starting with a fever and flu-like symptoms and rash 	<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>

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 VASODRINE contains

Active ingredient (main ingredient)	midodrine hydrochloride
Other ingredients (inactive ingredients)	microcrystalline cellulose maize starch magnesium stearate colloidal anhydrous silica

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

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

This medicine is not addictive.

What VASODRINE looks like

VASODRINE 2.5 mg (containing 2.5 mg of midodrine hydrochloride) are white, flat, round tablets with 7 mm diameter and embossed with "2.5"
(AUST R 309183).

VASODRINE 5 mg (containing 5 mg of midodrine hydrochloride) are white, flat, round tablets with 10 mm diameter and embossed with "5".
(AUST R 309184).

Available in blisters of 60, 90 and 500 tablets.

Not all strengths and presentations may be marketed.

Who distributes VASODRINE

Southern XP Pty Ltd
Unit 5/118 Church St
Hawthorn, VIC, 3122
Australia

Sponsor:

Southern XP IP Pty Ltd
Unit 5/118 Church Street
Hawthorn, VIC, 3122
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This leaflet was prepared in August 2025.