

▼ This medicine is subject to additional monitoring. 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.

Vasodrine

midodrine hydrochloride (mid-OH-drean HIGH-droe-KLOR-ide) – tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Vasodrine.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT VASODRINE IS USED FOR

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

Vasodrine contains the active ingredient(s) midodrine hydrochloride.

Midodrine hydrochloride belongs to a group of medicines called adrenergic agents.

It works by raising your blood pressure.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

BEFORE YOU TAKE VASODRINE

When you must not take it

Do not take this medicine if you have an allergy to:

- midodrine hydrochloride the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines.

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

Do not take this medicine if you have any of the following medical conditions:

- high blood pressure
- a slow pulse
- certain forms of cardiovascular disease e.g. heart attack, heart failure, blood vessel disease, changes in heart rhythm
- elevated pressure in the eye (glaucoma) or poor vision because of damage to the eye caused by diabetes
- an overactive thyroid gland (hyperthyroidism)
- hormonal disorders caused by a rare tumour in the adrenal gland, which sits near the kidney (phaeochromocytoma)

- difficulty passing urine
- severe kidney disease or inflammation of the kidneys
- prostate problems

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.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Talk to your doctor before taking Vasodrine if you have been told 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.

Tell your doctor if you have or have had any of the following medical conditions:

- 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
- 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
- a disease of the prostate, as you may find passing urine is difficult when taking Vasodrine
- Your doctor will perform some tests such as checking your kidney function and blood pressure before you start using this medicine.

Tell your doctor if you have diabetes.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Using this medicine while pregnant or breastfeeding is not recommended.

Do not give this medicine to children and adolescents under the age of 18.

The safety and efficacy of Vasodrine in children has not been established.

If you have not told your doctor about any of the above, tell him/her before you start taking Vasodrine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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).
- 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 methyl dopa
- 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 heart beat. 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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO TAKE VASODRINE

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 doctor or pharmacist for help.

How much to take

Your doctor will decide your dose and tell you how long you should take this medicine.

The recommended starting dose is one 2.5 mg tablet three times each day. This dose

may be increased weekly up 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.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Vasodrine may not work as well and your problem may not improve.

How to take it

Swallow the tablets whole with a full glass of water. The tablets may be taken with food.

When to take Vasodrine

Take your medicine 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 the 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.

How long to take Vasodrine

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 forget to take it

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 that 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 have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26) for advice or go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have taken too much Vasodrine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include:

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

WHILE YOU ARE TAKING VASODRINE

Things you must do

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 must 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.

Things to be careful of

Be careful driving or operating machinery until you know how Vasodrine affects you. This medicine may cause dizziness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Vasodrine.

All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- goose bumps
- headache
- nausea (feeling sick)
- heartburn
- flushing
- chills
- increased tear production
- sleep disturbances including difficulty sleeping

Tell your doctor as soon as possible if you notice any of the following:

- abdominal pain
- being sick (vomiting)
- diarrhea
- 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

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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 heart beat
- 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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

Other side effects not listed above may also occur in some people.

AFTER TAKING VASODRINE

Storage

Keep your medicine in the original container. If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Vasodrine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

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.

PRODUCT DESCRIPTION

What it looks like

Vasodrine 2.5 mg – White, flat, round tablets with 7 mm diameter and embossed with “2.5”

Vasodrine 5 mg – White, flat, round tablets with 10 mm diameter and embossed with “5”.

Available in blisters of 60, 90 and 500 tablets.

Not all strengths and presentations may be marketed.

Ingredients

Active ingredients:

Vasodrine 2.5 mg –
2.5 mg midodrine hydrochloride

Vasodrine 5 mg –
5 mg midodrine hydrochloride

Inactive ingredients:

- microcrystalline cellulose
- maize starch
- magnesium stearate
- colloidal anhydrous silica

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

Supplier

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, 3122, Victoria
Australia

Australian Register Number(s)

2.5 mg tablets: AUST R 309183

5 mg tablets: AUST R 309184

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