

VASOREX

Amlodipine besylate tablets 2.5 mg, 5 mg, and 10 mg

What is in this leaflet

The information enclosed answers several general questions about VASOREX.

This leaflet does not include all the accessible information on VASOREX.

All medication has benefits and risks. Your doctor will have considered the risks of you using VASOREX against the benefits expected.

Discuss with your doctor any concerns you may have.

This leaflet was last updated on the date at the end of this leaflet.

Keep this information with your medicine and refer to this leaflet if you have any queries.

What VASOREX is used for

VASOREX tablets are used for the treatment of:

- Hypertension (high blood pressure)

Blood pressure should be regularly checked as hypertension typically does not have any obvious symptoms. Hypertension can cause serious health issues if not managed effectively.

- Chronic chest pain that occurs when the heart does not get enough oxygen-rich blood (angina), including a specific type of angina known as Prinzmetal's angina pectoris.

VASOREX helps to prevent chest pain due to a shortage of oxygen-rich blood to the heart. It is not for the relief of a sudden angina attack. Your doctor will have prescribed you a "reliever" medication for sudden-onset chest pain.

VASOREX tablets contain the active ingredient amlodipine, which belongs to the group of medicines known as calcium channel blockers or calcium channel antagonists. Calcium channel blockers block the entry of calcium into the heart muscle cells and blood vessel walls. This reduces electrical conduction in the heart and widens blood

vessels, making it easier for the heart to pump, increasing the supply of oxygen-rich blood to the heart and lowering blood pressure.

You may also be prescribed other heart medications to be used with VASOREX to treat your heart condition.

Your doctor may have prescribed VASOREX for a different reason.

If you have any concerns about why VASOREX has been prescribed, please discuss this with your doctor.

VASOREX is only accessible with a prescription from your doctor.

VASOREX is not approved for the use in individuals under 18 years of age.

Before you use VASOREX

If you have any concerns about using VASOREX, ask your doctor or pharmacist.

Do not use VASOREX if you:

- are allergic to amlodipine, or any of the other ingredients in VASOREX (listed on the back of this leaflet).
- are allergic to any other type of calcium channel blocker, for example: medications containing felodipine, lercanidipine or nifedipine.

Seek immediate medical attention if you experience any of the following side effects, as you may be allergic to this medicine:

- Itching, rash, or reddened skin.
- Swelling of the eye lids, lips, face, and throat.
- Increase in wheezing and shortness of breath.
- Feeling faint or dizzy.

If you have any concerns if VASOREX is right for you, discuss with your doctor.

Please inform your doctor **before** using VASOREX if you are currently being treated or have in the past been treated for any other medical conditions, in particular the following:

- have heart failure or other heart problems.
- have liver problems.
- have an allergy to any dyes, preservatives, foods, or other medications.
- are pregnant, trying to get pregnant or breastfeeding.

Using other medicines

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including any medicines obtained without a prescription from your pharmacy, health store or supermarket.

If you use VASOREX with some other medications the effect of VASOREX or the other medicine may be altered. These involve:

- Other medication for the treatment of angina or high blood pressure, for example, diltiazem.
- Some medication used for the treatment of fungal infections, for example, itraconazole or ketoconazole.
- Several antibiotics, for example, clarithromycin, erythromycin, or rifampicin.
- Anti-proteases, medication used for the treatment of HIV, for example ritonavir.
- Immune-suppressing medications, for example: cyclosporin, everolimus, sirolimus or tacrolimus.
- Simvastatin, a medication used to help lower cholesterol.
- St. John's Wort.
- Temsirolimus, a medication used for the treatment of kidney cancer.

Your doctor will discuss with you what to do if you are taking any of the above medications. Your doctor may instruct you to take a modified amount of the above medications or you may be instructed to change your medication completely.

Pregnancy and breast-feeding

VASOREX should not be used if you are pregnant, planning to become pregnant or breast-feeding, unless you are advised to do so by your doctor. You and your doctor should talk about the best way to control your blood pressure or angina while you are pregnant or breast-feeding.

Do not use after the expiry date. The expiry date can be found on the label on the plastic bottle or on the carton (if provided).

If the packaging of the VASOREX carton or plastic bottle displays signs of damage or tampering do not use.

How to use VASOREX

VASOREX comes in three different strength tablets. Your doctor will have decided which strength you need and how many tablets to take. This information will also be written on the pharmacist's label on the VASOREX container and may differ from the information contained in this leaflet.

It is important that you follow the prescribed instructions your doctor gave you, on the dosage of VASOREX, and the duration you should take it.

Check with your doctor or pharmacist if you do not understand the instructions provided with this medication.

How much VASOREX to take and how to take it

The standard starting dose for VASOREX is 5 mg per day. The dose may be increased to the maximum recommended dose of 10 mg per day if your doctor feels it is necessary.

VASOREX is not approved for use in individuals aged younger than 18 years.

Swallow the VASOREX tablet with a large glass of water. Do not crush or chew the tablets.

You can take VASOREX with or without food.

Try to take VASOREX at about the same time or times each day to avoid missing any of your doses.

To get the full benefit from VASOREX, you should take it exactly as your doctor has prescribed.

How long to take VASOREX

VASOREX is a long-term treatment. It is essential that you continue to take VASOREX even when you feel in good health.

While taking VASOREX, your doctor will monitor your progress closely to make sure the medicine is working as it should. Make sure you continue to take VASOREX for as long as your doctor thinks is necessary.

If you forget to take your VASOREX Tablets

If you have forgotten to take your normal dose at the correct time, take your next dose as soon as you remember. However, if you forget to take VASOREX close to the time of the next dose then simply miss out the dose you have forgotten.

Do not take a double dose of VASOREX at any given time if you have missed a dose.

If you have difficulty remembering when your next dose of VASOREX is due, talk to your pharmacist for advice.

While you are using VASOREX

Abide by all instructions given by your doctor carefully as they may be different from the information provided in this leaflet.

Make sure you attend all doctor's appointments in relation to your treatment with VASOREX so that your progress can be reviewed.

While taking VASOREX you will have regular appointments with your doctor so they can make sure the treatment is working as it should and perform tests if required.

If you are about to start taking any other medicine while you are using VASOREX, tell your doctor, pharmacist, and dentist.

Tell your doctor without delay if you become pregnant whilst you are taking VASOREX.

Important Advice

This medicine has been prescribed for you personally. Do not give it to anyone else even if their symptoms are the same as yours, as it may harm them.

VASOREX should not be used to treat any other health condition, except if your doctor advises you to.

Do not suddenly stop taking VASOREX or change your dose of VASOREX before you have spoken with your doctor.

Do not start taking any other medicines, including medicines obtained without a prescription or herbal medicines, without first talking to your doctor or pharmacist.

Do not consume large amounts of grapefruit juice or eat a lot of grapefruit while using VASOREX, as it may increase the blood pressure-lowering effects of the medicine.

Grapefruit may change how various medications are metabolised in the body.

The components of grapefruit juice may intensify the effects of VASOREX if consumed in large quantities of 1.2 litres or more.

Take care when driving or using machines until you are aware of how VASOREX may affect you. If you do experience dizziness or tiredness while taking VASOREX, you should not drive or operate machinery.

Lifestyle changes to help your angina or high blood pressure

Your doctor may suggest some of the below lifestyle changes that may help to manage your condition.

- Alcohol: Limit alcohol use.
- Diet: Decrease the amount of salt used in your diet.
- Losing weight: For some people, the help of a dietician may be required to plan an appropriate diet.
- Regular exercise: This helps by strengthening the heart and lowering blood pressure. Please note that prior to starting out on a regular exercise regimen, speak to your doctor about appropriate exercises for you. If you experience

discomfort, chest pain or become short of breath when exercising, tell your doctor.

- Smoking: Stopping smoking or decreasing the number of cigarettes you smoke can help.

In case of overdose

If you have received more VASOREX than you should (overdose):

If you or someone else takes too much VASOREX, immediately phone the Poisons Information Centre (telephone 0800 POISON or 0800 764 766) or your doctor or go to your nearest Accident and Emergency department even if you do not feel unwell or there are no signs of overdose symptoms.

It is possible you require urgent medical attention.

Keep these telephone numbers and information in an easily accessible place.

Signs and symptoms of an overdose may include:

- Dizziness or fainting.
- Very fast heartbeat.
- Uneven heartbeat.

Side Effects

Discuss with your doctor or pharmacist any questions or concerns you may have.

All medications can have side effects. For most people who experience side effects they are usually mild and pass over a short time. At times they can be serious, and some side effects may require you to have medical treatment.

Discuss with your doctor if you experience any changes to your condition as it can sometimes be difficult to determine whether changes are a result of your condition, or a side effect from taking VASOREX or another medication.

Do not be concerned by the side effects below, however, if you experience any of the below side effects and they are causing concern, please talk to your doctor or pharmacist, but do not stop using VASOREX.

Common side effects (affecting more than 1% but less than 10% of VASOREX) users:

- Abdominal pain.
- Dizziness.
- Drowsiness.
- Flushing.
- Headache.

- Heart palpitations.
- Nausea.
- Tiredness.

The following may not be related to VASOREX use, however if you experience any of the below and they are causing concern, please talk to your doctor:

- Indigestion.
- Sexual concerns.

If you are aged 65 years or older, the possibility of experiencing side effects is increased, for example; dizziness, muscle cramps and/or swelling of the ankles and feet. Discuss with your doctor any side effects you have experienced.

The side effects below can be serious. If you experience any of the below, immediately tell your doctor or seek medical attention:

- Feeling dizzy or lightheaded when standing up from lying down or a seated position.
- Feeling weak or unusually tired.
- Heartbeat changes.
- Liver disease symptoms, for example, dark coloured urine, itching or yellowing of the eyes or skin.
- Mood changes, for example, feeling more nervous or anxious.
- Movements that are unusual, for example, shaking and/or trembling of the hands, stiffness in the body, twisted body movements and a shuffling walk.
- Muscle aches or muscle cramps.
- Numbness or tingling in the feet or hands.
- Pain in the eyes and/or vision change.
- Pain in the joints.
- Swelling of the body or parts of the body.

Go immediately to your nearest hospital or Accident and Emergency Department if you experience the following side effects:

- Allergy symptoms, for example, itching and/or a skin rash.
- Heartbeat that is irregular or fast.
- Pain in the chest.
- Pain in the chest that is related with angina that is more severe, has a longer occurrence or happens more often.
- Shortness of breath.
- Upper abdominal pain that is severe and may be accompanied with nausea.

If you experience any other side effects that are not discussed above, tell your doctor without delay.

After using VASOREX

Storage of VASOREX Tablets

Keep out of reach of children by storing VASOREX in a locked cabinet at a height that is hard to reach for children.

Avoid direct sunlight or heat. Do not store VASOREX in your car on a hot day or on a windowsill.

Store VASOREX below 25°C. Protect from light and moisture.

Keep VASOREX tablets in their container until you are about to take them.

The expiry is the last day of the month of the expiry date.

Disposal

If your doctor advises you to stop taking VASOREX, or they have exceeded their expiry date, request information from your pharmacist on what to do with any product that is left over.

Product Description

What VASOREX looks like

VASOREX is the brand name of your medicine.

VASOREX tablets come in three different strengths:

- VASOREX 2.5 mg tablets are white to off white, round with “C” debossed on one side and “126” on the other side.
- VASOREX 5 mg tablets are white to off white, round with “C” debossed on one side and “127” on the other side.
- VASOREX 10 mg tablets are white to off white, round with “C” debossed on one side and “128” on the other side.

VASOREX 2.5 mg tablets are available in plastic bottles of 90 tablets.

VASOREX 5 mg tablets are available in plastic bottles of 90 tablets.

VASOREX 10 mg tablets are available in plastic bottles of 90 tablets.

Ingredients

The active ingredient in a VASOREX tablet contains either 2.5 mg, 5 mg, or 10 mg of amlodipine.

Each VASOREX tablet also contains microcrystalline cellulose, dibasic calcium phosphate, sodium starch glycollate, magnesium stearate and colloidal anhydrous silica.

VASOREX does not contain gluten or lactose.

Sponsor Details

VASOREX is supplied in New Zealand by:

REX Medical Ltd
PO Box 18-119
Glen Innes
AUCKLAND.
Ph: (09) 574 6060
admin@rexmed.co.nz

Date of Preparation

This leaflet was prepared on 14 August 2020.

©REX Medical Ltd, New Zealand.

VASOREX® is a registered trademark.