

Perivasc

contains the active ingredient amlodipine besylate

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about PERIVASC.

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 PERIVASC 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 Perivasc is used for

PERIVASC is used to lower high blood pressure (hypertension). There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems.

PERIVASC belongs to a group of medicines called calcium channel blockers or calcium ion antagonists. They work by widening your blood vessels, making it easier for your heart to pump blood around the body and help increase the supply of blood and oxygen to your heart. Calcium channel blockers do not change the amount of calcium in your blood or bones.

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

Your doctor may have prescribed Perivasc for another reason.

PERIVASC is also used to treat angina pectoris. Angina is a pain or uncomfortable feeling in the chest, often spreading to the arms or neck, and sometimes to the shoulders and back. The pain of angina is due to a shortage of oxygen to the heart.

PERIVASC is not for the relief of a sudden attack of angina. Your doctor will have given you other medication to treat this. Your doctor may have prescribed PERIVASC for another purpose.

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

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

Before you take Perivasc

When you must not take it

Do not take PERIVASC if:

- * **you have ever had an allergic reaction to PERIVASC or other calcium channel blockers.**

These medicines include felodipine (Plendil ER, Agon SR, Felodur ER), nifedipine (Adalat, Adalat Oros, Nifecard, Nifedipine-BC, Nifehexal, Nyefax, SBPA Nifedipine) or lercanidipine (Zanidip) (Not all

brands are given). Check with your doctor or pharmacist if you are unsure.

Some of the symptoms of an allergic reaction to PERIVASC may include a skin rash similar to hives, itchiness, shortness of breath, swelling of the face, lips or tongue.

- * you are allergic to any of the ingredients listed at the end of this leaflet.
- * PERIVASC is not recommended for use in children as there have been no studies of its effects in children.

If you are not sure whether you should be taking PERIVASC, talk to your doctor.

Do not take PERIVASC if:

- * the packaging shows signs of tampering or does not look quite right.
- * the expiry date marked on the packaging has passed, even though the tablets may look alright.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

Tell your doctor if:

- * you are pregnant or intend to become pregnant while taking PERIVASC.

Medicines like PERIVASC may affect the developing baby if you take it during pregnancy. Your doctor will discuss the possible risks and benefits of taking PERIVASC during pregnancy.

- * you are breastfeeding or wish to breastfeed.

Your doctor will discuss the risks and benefits of taking PERIVASC when breastfeeding.

- * you are allergic to any foods, dyes, preservatives or any other medicines.
- * you have any health problems, including:
 - heart disease such as heart failure
 - liver problems
 - any other allergies

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and PERIVASC may interfere with each other.

Your doctor or pharmacist has a complete list of medicines to be careful with or avoid while taking PERIVASC.

If you have not told your doctor or pharmacist about these things, tell them before you start taking PERIVASC.

How to take Perivasc

Take PERIVASC exactly as your doctor has prescribed.

Follow all directions given to you by your doctor or pharmacist. They may differ from the information contained in this leaflet. If you do not understand the instructions on the box ask your doctor or pharmacist for help.

How much to take

The usual dose of PERIVASC is one 5 mg tablet each day. Your doctor may increase this to one 10 mg tablet each day.

Your doctor may prescribe another

dose of PERIVASC depending on your condition and how you respond to this medicine.

How to take it

Swallow the tablet whole with a full glass of water.

Take your tablet at about the same time each day, either morning or evening.

Taking your tablet at the same time each day will have the best effect. It will also help you to remember when to take it. PERIVASC can be taken with or without food.

How long to take it

You must take PERIVASC every day. Continue taking your medicine for as long as your doctor tells you.

If you forget to take it

If you miss a dose and it is less than 12 hours from when you should take it, take it straight away, then continue as normal the next day. Otherwise, skip that day's dose but be sure to take the next day's dose when it is due.

Do not take a double dose to make up for the dose that you missed.

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre - the telephone number in Australia is 131 126 and in New Zealand is 0800 POISON or 0800 764 766 or go to Accident and Emergency (Casualty) at your nearest hospital if you think you or anyone else may have taken too much PERIVASC. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too many tablets, you

may feel dizzy, lightheaded or faint and have an irregular heart beat.

While you are taking Perivasc

Things you must do

Tell any other doctors, dentists and pharmacists who are treating you that you are taking PERIVASC.

If you are about to start any new medicine, tell your doctor or pharmacist that you are taking PERIVASC.

If you become pregnant while taking PERIVASC tell your doctor immediately.

Things you must not do

Do not take PERIVASC to treat any other conditions unless your doctor says to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how PERIVASC affects you.

PERIVASC may cause dizziness or drowsiness in some people and affect alertness.

If this occurs, do not drive, operate machinery or do things that could be dangerous if you are not alert.

Things that would be helpful for your high blood pressure or angina

Some self-help measures suggested below may assist your condition.

Talk to your doctor about these for more information.

- * **Weight:** Your doctor may suggest losing some weight. Some people may need a dietician to plan a suitable diet to

help with weight loss.

- * **Exercise:** Regular exercise helps lower blood pressure and strengthen the heart. It is important not to overdo it. Before commencing regular exercise you should consult your doctor who will suggest the most suitable exercise for you. If you feel uncomfortable when exercising or experience symptoms such as unusual chest pain or breathlessness see your doctor.
- * **Alcohol:** Your doctor may advise you to limit your alcohol intake.
- * **Salt:** Your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake you should avoid using salt at the table or in cooking.
- * **Smoking:** Your doctor may advise you to stop smoking or at least cut down.

Side effects

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

PERIVASC helps most people but it may have some unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Tell your doctor if you experience any of the following and they worry you:

- * swelling of the ankles, feet, face or hands
- * headache
- * dizziness
- * flushing
- * palpitations
- * tiredness

- * drowsiness or sleepiness
- * stomach pain or nausea
- * indigestion
- * unusual tiredness or weakness

These are the more common side effects of PERIVASC.

Tell your doctor if you experience any of the following:

- * muscle cramps or aches
- * sexual problems
- * swollen gums
- * constipation
- * weight gain
- * sleeplessness
- * feeling nervous, depressed or moody
- * changes in vision or sight
- * loss or thinning of hair
- * ringing in the ears

These may or may not be due to PERIVASC but you should tell your doctor if they worry you.

Tell your doctor immediately if you notice any of the following:

- * changes in heart beat either fast or slow
- * chest pain
- * dizziness or lightheadedness on standing up from a sitting or lying position
- * shortness of breath
- * symptoms of allergy such as skin rash and/or itching
- * symptoms of liver disease such as itching, yellowing of the skin and eyes, and dark coloured urine

These may be serious side effects that may need urgent medical attention. Serious side effects are rare.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

If you notice any other symptoms that worry you, check with your doctor.

Ask your doctor or pharmacist if you don't understand anything in this list.

If you are 65 years or older, you should be especially careful while

taking PERIVASC. Report any side effects promptly to your doctor.

Some people in this age group may be more likely to experience side effects such as swelling of the feet and ankles, muscle cramps and dizziness.

After taking Perivasc

Storage

Keep your tablets in the pack until it is time to take them.

If you take your tablets out of the pack they will not keep as well.

Keep your tablets in a cool dry place where temperatures stay below 30 degrees C.

Do not store PERIVASC or any other medicine in the bathroom or near a sink.

Do not leave your medicines on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep PERIVASC 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 PERIVASC, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

PERIVASC Tablets are available in two strengths:

- * PERIVASC 5 mg - white, scored and marked NVC/5.
- * PERIVASC 10 mg - white, scored and marked NVC/10 on one side.

A box contains 30 tablets.

Ingredients

Active ingredients

- * PERIVASC 5 mg Tablets contain amlodipine besylate equivalent to amlodipine 5 mg.
- * PERIVASC 10 mg Tablets contain amlodipine besylate equivalent to amlodipine 10 mg.

Other ingredients

- * microcrystalline cellulose
- * calcium hydrogen phosphate
- * sodium starch glycollate
- * magnesium stearate

PERIVASC does not contain gluten, sugar or lactose.

Supplier

PERIVASC is supplied in Australia by:

Alphapharm Pty Limited
(ABN 93 002 359 739)
Chase Building 2
Wentworth Park Road
Glebe NSW 2037

Phone: (02) 9298 3999

Medical Information

Phone: 1800 028 365

Australian Registration Numbers:

PERIVASC 5 mg - AUST R 123354
PERIVASC 10 mg - AUST R 123355.

This leaflet was prepared in April 2007