

PERISYL®

perindopril erbumine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PERISYL.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking PERISYL against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What PERISYL is used for

The active ingredient of PERISYL, perindopril belongs to a group of medicines called Angiotensin Converting Enzyme Inhibitors (ACE Inhibitors).

PERISYL is available only with a doctor's prescription.

PERISYL lowers high blood pressure, a condition which doctors call hypertension.

Everyone has blood pressure. This pressure helps get your blood all around the body. Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have high blood pressure when your blood pressure stays higher than is needed, even when you are calm or relaxed.

There are usually no symptoms of high blood pressure. The only way of knowing that you have it 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. You may feel fine and have no symptoms, but eventually it can cause stroke, heart disease and kidney failure.

PERISYL helps lower your blood pressure.

You may be prescribed PERISYL for heart failure.

Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure is not the same as heart attack and does not mean that the heart stops working. Some people develop heart failure after having had a heart attack. However there are also other causes of heart failure.

Heart failure may start off with no symptoms, but as the condition progresses, you may feel short of breath or may get

tired easily after light physical activity such as walking. You may wake up short of breath at night. Fluid may collect in different parts of the body, often first noticed as swollen ankles and feet. In severe heart failure, symptoms may occur even at rest.

PERISYL helps to treat heart failure. If you follow your doctor's advice, your ability to perform daily activities may improve. You may breathe more easily, feel less tired, and have less swelling.

You may also have been prescribed PERISYL if you have coronary artery disease.

Coronary artery disease is narrowing of the vessels carrying blood to the heart. In patients with coronary artery disease, PERISYL has been shown to reduce some of the risks, including heart attacks.

Before you take PERISYL

There are some people who shouldn't take PERISYL. Please read the list below. If you think any of these situations apply to you or you have any questions, please consult your doctor.

Do not take PERISYL if:

- you are allergic to perindopril, any other ACE inhibitor or any of the ingredients listed at the end of this leaflet
- you have experienced symptoms such as wheezing, swelling of the face, tongue, lips or throat, intense itching or severe skin rashes with previous ACE inhibitor

treatment or if you or a member of your family have had these symptoms either spontaneously or, in response to another medicine in the past (a rare condition called angioedema)

- you are pregnant or plan to become pregnant
- you are breastfeeding or plan to breastfeed
- you undergo treatments where your blood is treated outside of the body (also known as extracorporeal treatments) that may increase your risk of allergic reactions, treatments such as:
 - renal dialysis or haemofiltration using polyacrylonitrile membranes
 - low-density lipoprotein (LDL) apheresis, a technique where LDL is 'filtered' out of the blood, using dextran sulfate
- you are treated with a blood pressure lowering medicine containing aliskiren and have diabetes or impaired kidney function
- you have kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis)
- you are treated with sacubitril/ valsartan a medicine used to treat long-term heart failure as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased (see also 'Tell Your Doctor Straight Away' and 'Taking Other Medicines' sections)

- the packaging is damaged or shows signs of tampering
- The expiry date (EXP) on the pack has passed.

Tell your doctor straight away if:

- you are pregnant or become pregnant while taking PERISYL, as it may cause serious harm to your baby.
- you are undergoing desensitisation treatment, or have had an allergic reaction during previous desensitisation treatment (e.g. treatments using bee, wasp or ant venom).
- you are undergoing, or you are intending to undergo, treatments where your blood is treated outside of the body (also known as extracorporeal treatments).
- you are to undergo anaesthesia and/or surgery.
- you have recently suffered from diarrhoea or vomiting or are dehydrated.
- you are on a salt restricted diet or use salt substitutes which contain potassium.
- you have an intolerance to some sugars as PERISYL contains lactose.
- you are taking lithium (used to treat mania or depression).
- you are taking any of the following medicines used to treat high blood pressure:
 - an 'angiotensin II receptor blocker' (also known as ARBs or sartans - for example valsartan, telmisartan,

irbesartan), in particular if you have diabetes-related kidney problems

- aliskiren
- you have any other health problems, including:
 - kidney disease, or if you are on renal dialysis
 - aortic stenosis (narrowing of the main blood vessel leading from the heart)
 - liver disease
 - high or low levels of potassium, or other problems with salt balance.
 - diabetes
 - low blood pressure
 - heart disease, including hypertrophic cardiomyopathy (heart muscle disease)
 - systemic lupus erythematosus or scleroderma (a disease affecting the skin, joints and kidneys)
 - are of African origin since you may have a higher risk of angioedema and this medicine is less effective in lowering your blood pressure
 - have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism).

If you think any of these situations apply to you, or you have any doubts or questions about taking PERISYL consult your doctor or pharmacist.

Taking other medicines

Taking PERISYL may change the effect of some medicines, and some medicines may affect how well PERISYL works. You may need different amounts of your medication or to take different medicines. The medicines that may interact with PERISYL include the following:

- some medications used to treat high blood pressure (including angiotensin receptor blockers), aliskiren (see also 'Do Not Take PERISYL If' and 'Tell Your Doctor Straight Away' sections), diuretics (sometimes called "fluid" or "water" tablets because they increase the amount of urine passed each day)
- some treatments where your blood is treated outside of the body, also known as extracorporeal treatments (see also 'Do Not Take PERISYL If' and 'Tell Your Doctor Straight Away' sections)
- some antibiotics and medicines used to treat infections
- some anti-inflammatory drugs (including high dose aspirin, ibuprofen) for pain relief
- medicines used to treat mood swings and some types of depression (lithium, tricyclic antidepressants, antipsychotics)

- potassium-sparing diuretics, sources of potassium, like potassium tablet and salt substitutes containing potassium, other drugs which can increase potassium in your body (such as heparin, a medicine used to thin blood to prevent clots; co-trimoxazole also known as trimethoprim/sulfamethoxazole for infections caused by bacteria; and ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection)
- immunosuppressants (medicines which reduces the activity of the body's natural defences)
- vasodilators including nitrates
- medicines used to treat diabetes (tablets and insulin)
- medicines which may affect the blood cells, such as allopurinol, procainamide
- baclofen (a medicine used to treat muscle stiffness in diseases such as multiple sclerosis)
- medicines used for the treatment of low blood pressure, shock or asthma [e.g. ephedrine, noradrenaline or adrenaline (epinephrine)]
- gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis)
- medicines which may increase the risk of angioedema (a severe allergic reaction) such as:

- mammalian target of rapamycin (mTOR) inhibitors used to avoid rejection of transplanted organs (e.g. temsirolimus, sirolimus, everolimus)
- sacubitril (available as fixed-dose combination with valsartan), used to treat long-term heart failure (see also 'Do Not Take PERISYL If' and 'Tell Your Doctor Straight Away' sections)
- gliptins used to treat diabetes (e.g. linagliptin, saxagliptin, sitagliptin, vildagliptin, alogliptin).

It is a good idea to remind your doctor of all other medicines you take. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking PERISYL.

For older people or children

PERISYL can generally be used safely by elderly people. However reduced kidney function is often found in elderly people and in this case, the starting dose should always be 2 mg.

PERISYL is not recommended for children.

How to take PERISYL

The dose of PERISYL you may need each day will be decided and adjusted by your doctor. This will normally be 2 mg, 4 mg or 8 mg once daily for high blood pressure and for people with coronary artery disease, and 2 mg to 4 mg once daily for heart failure.

Swallow the tablet(s) with water, preferably in the morning before a meal.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

How long to take it

PERISYL helps control your blood pressure, or heart failure or coronary artery disease but does not cure it. Continue taking the tablets for as long as your doctor tells you.

If you take too much (overdose)

Taking too much PERISYL (an overdose) may cause low blood pressure (also known as hypotension). The most likely effect in case of overdose is low blood pressure which can make you feel dizzy or faint. If this happens, lying down with the legs elevated can help. Other effects like sickness, cramps, sleepiness, confusion, kidney problems, salt and water disturbances are possible.

Immediately telephone your doctor or the Poisons Information Centre (telephone 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 PERISYL. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking PERISYL

Things you must do

Take PERISYL exactly as your doctor has prescribed. Otherwise you may not get the benefits from treatment. Tell all doctors, dentists and pharmacists who are involved with your treatment that you are taking PERISYL.

Make sure you drink enough water during exercise and hot weather especially if you sweat a lot. This will help you avoid any dizziness or light-headedness caused by a sudden drop in blood pressure.

Tell your doctor straight away if you have excessive vomiting or diarrhoea while taking PERISYL.

Things you must not do

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

Do not take PERISYL 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 stop taking your tablets because you are feeling better, unless advised by your doctor.

Things to be careful of

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

This medicine may cause dizziness or weariness due to low blood pressure in some people, particularly at the start of treatment or when PERISYL is taken with another blood pressure lowering medicine. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

PERISYL helps most people with high blood pressure, heart failure or coronary artery disease, but it may have unwanted side effects in a few people. While these side effects when they occur are usually mild they can be serious.

Angioedema (a severe allergic reaction) has been reported in patients treated with ACE inhibitors, including PERISYL. This may occur at any time during treatment. If you develop such symptoms described below you should tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital. These side effects are extremely rare but can become serious:

- swelling of your extremities (limbs, hands or feet), lips, face, mouth, tongue or throat
- a fast and irregular heartbeat
- purple spots with occasional blisters on the front of your arms and legs and/or around your neck and ears (a rare condition known as Stevens-Johnson Syndrome)
- difficulty in breathing
- severe blisters, skin rash, itching, erythema multiforme or other allergic reactions.

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

Common (may affect up to 1 in 10 people) side effects can include:

- cough, often described as dry and irritating, shortness of breath, discomfort on exertion
- headache, dizziness, vertigo, pins and needles
- changes in the rhythm or rate of the heartbeat, fast or irregular heartbeat
- feeling tired, lethargic or weak
- tinnitus (persistent noise in the ears), vision disturbances
- hypotension, flushing, impaired peripheral circulation, vasculitis, nose bleeds
- nausea, vomiting, taste disturbances, indigestion, diarrhoea, constipation, stomach pain or discomfort
- muscle cramps
- rash, pruritus (itching)

Uncommon (may affect up to 1 in 100 people) side effects can include:

- depression
- high levels in the blood of potassium, urea and/or creatine, low sodium levels in the blood
- mood disturbance, sleep disturbances (difficulty sleeping, abnormal dreams), feeling sleepy or drowsy, fainting
- difficulty breathing or wheezing

- dry mouth
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- excessive sweating
- increased sensitivity of the skin to sun, skin rash or inflammation of the skin often including blisters that weep and become crusted
- increase in some white blood cells
- erectile dysfunction
- fever or high temperature
- chest pain
- kidney problems
- decreased blood sugar levels
- aching muscles, muscle tenderness or weakness, not caused by exercise
- generally feeling unwell
- falls.

Rare (may affect up to 1 in 1,000 people) side effects can include:

- elevation of bilirubin levels in the blood, increases in liver enzymes
- worsening of psoriasis
- kidney disease
- problems with production or passing of urine.
- concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits which may be due to inappropriate anti-diuretic hormone (ADH) secretion can occur with ACE inhibitors. If you have these symptoms contact your doctor as soon as possible.

Very rare (may affect up to 1 in 10,000 people) side effects can include:

- hepatitis
- inflammation of the pancreas (pancreatitis)
- eosinophilic pneumonia
- runny or blocked nose, sneezing, facial pressure or pain
- red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body
- joint pain
- swelling of hands, ankles or feet

- bleeding or bruising more easily than normal caused by a low blood platelet count, frequent infections such as fever, severe chills, sore throat or mouth ulcers caused by a lack of white blood cells, pancytopenia (a rare type of anaemia)
- illnesses resulting from a lack of red blood cells
- stroke, myocardial infarction, angina pectoris (a feeling of tightness, pressure or heaviness in the chest)
- changes in the rhythm or rate of the heartbeat
- confusion or hallucinations.

Not known (frequency cannot be estimated from the data available):

- discolouration, numbness and pain in fingers or toes (Raynaud's phenomenon)

Consult your doctor, pharmacist or nurse if you experience any of these or notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them. Other uncommon side effects have been reported and you should ask your doctor, pharmacist or nurse if you want to know more.

After taking PERISYL

Storage

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

If you take the tablets out of the pack they may not keep well.

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

Do not store PERISYL 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, return any leftover tablets to your pharmacist for disposal.

Product description

What it looks like

PERISYL 2 mg

Green coloured mottled, round, biconvex tablets debossed with “PT” over “2” on one side of the tablet & “M” on the other side. Available in blister packs of 30.

PERISYL 4 mg

Green coloured mottled, capsule shaped, biconvex tablets with side notch debossed with “PT4” on one side of the tablet & “M” on the other side. Available in blister packs of 30.

PERISYL 8 mg

Green coloured mottled, round, biconvex tablets debossed with “PT8” on one side of the tablet & “M” on the other side. Available in blister packs of 30.

Ingredients

PERISYL contains 2 mg, 4 mg and 8 mg of perindopril erbumine as the active ingredient.

It also contains the following inactive ingredients:

- colloidal anhydrous silica
- sodium bicarbonate
- lactose
- microcrystalline cellulose
- magnesium stearate
- chlorophyllin-copper complex aluminium lake

Supplier

PERISYL is supplied in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in May 2022.

Australian registration numbers:

PERISYL 2 mg: AUST R 176516

PERISYL 4 mg: AUST R 176518

PERISYL 8 mg: AUST R 176517

PERISYL[®] is a Viatris company trade mark

Perisyl_cmi\May22/00