Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking PERISYL?

PERISYL contains the active ingredient perindopril erbumine. Perindopril belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors. PERISYL is used to lower high blood pressure, treat heart failure or coronary artery disease.

For more information, see Section <u>1. Why am I taking</u> PERISYL? in the full CMI.

2. What should I know before I take PERISYL?

Do not take if you have ever had an allergic reaction to perindopril, any other ACE inhibitor 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 PERISYL? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PERISYL 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 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 coronary artery disease; or 2 mg to 4 mg once daily for heart failure.

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

More instructions can be found in Section <u>4. How do I take PERISYL?</u> in the full CMI.

5. What should I know while taking PERISYL?

Things you should do

 Take this medicine exactly as prescribed and remind any

healthcare professional you are taking it. Make sure you drink enough water during exercise and hot weather especially if you sweat a lot. This will help you avoid 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 this medicine. Do not stop taking your Things you should not tablets because you are do feeling better, unless advised by your doctor. Do not give PERISYL to anyone else, even if they have the same condition as you. Take care when driving **Driving or using** or operating machinery machines until you know how PERISYL affects you. Dizziness or weariness due to low blood pressure may occur

	in certain patients. If you have any of these symptoms do not drive or operate machinery.
Looking after your medicine	 Store in a cool dry place below 25°C away from moisture, heat, and sunlight.
	 Keep your tablets in the pack until it is time to take them. Keep out of reach of children.

For more information, see Section <u>5. What should I know while taking PERISYL?</u> in the full CMI.

6. Are there any side effects?

All medicines can have side effects. Sometimes they are serious, most of the time they are not. If you do not feel well while you are taking PERISYL then tell your doctor or pharmacist as soon as possible. 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 swelling of your 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 after taking PERISYL - please seek urgent medical attention.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> effects? in the full CMI.

Active ingredient: perindopril erbumine

Consumer Medicine Information (CMI)

This leaflet provides important information about taking PERISYL. 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 PERISYL.

Where to find information in this leaflet:

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

1. Why am I taking PERISYL?

PERISYL contains the active ingredient perindopril erbumine. Perindopril belongs to a group of medicines called Angiotensin Converting Enzyme (ACE) Inhibitors.

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.

2. What should I know before I take PERISYL?

Warnings

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, or any other ACE inhibitor or any of the ingredients listed at the end of this leaflet.
 - Always check the ingredients to make sure you can take this medicine.
- 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 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 'What if I am 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
 - o aliskiren
 - sacubitril (available as fixed-dose combination with another medicine valsartan), used to treat long-term heart failure.

- you have any other health problems, including:
 - o 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 erythematous 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.

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. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Do not take if you are pregnant or plan to become pregnant.

Do not take if you are breastfeeding or plan to breastfeed.

It is important to tell your doctor if you are pregnant or intend to become pregnant, or if you are breastfeeding or intend to breastfeed.

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.

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.

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 if' 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 if' 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 if' 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.

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

4. How do I take PERISYL?

How much to take

• 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.

When to take PERISYL

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

If you forget to take PERISYL

PERISYL should be taken regularly at the same time each day.

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 it 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 PERISYL

If you think that you or anyone else has taken too much PERISYL, urgent medical attention may be needed.

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. You may require urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26) for advice, 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.

5. What should I know while taking PERISYL?

Things you should 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.

Call your doctor straight away or go to the Accident and Emergency department at your nearest hospital if you develop such symptoms described below:

- 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.

If you develop such symptoms described above 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.

Angioedema (a severe allergic reaction) has been reported in patients treated with ACE inhibitors, including PERISYL. This may occur at any time during treatment.

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

Things you should not do

- Do not give PERISYL 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.

Driving or using machines

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

Take care when driving or operating machinery until you know how PERISYL affects you.

Dizziness or weariness due to low blood pressure may occur in certain patients, 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.

Things to be careful of

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.

Looking after your medicine

- 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.
- Store below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

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.

Heat or dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

When to discard your medicine

Do not use this medicine after the expiry date.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking PERISYL, or the tablets have passed their expiry date, return any leftover tablets to your pharmacist for disposal.

6. Are there any side effects?

If you do not feel well while you are taking PERISYL then tell your doctor or pharmacist as soon as possible.

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
Gastrointestinal:	Speak to your doctor or
 nausea, vomiting, taste disturbances, indigestion, diarrhoea, constipation, stomach pain or discomfort 	pharmacist if you have any of these less serious side effects and they worry you.
 inflammation of the pancreas (pancreatitis) 	
Mouth:	
dry mouth	
 swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing 	
Kidney and liver related:	
 kidney problems elevation of bilirubin levels in the blood, increases in liver enzymes kidney disease problems with production or passing of urine 	

Less serious side effects | What to do concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits which may be due to inappropriate antidiuretic hormone (ADH) secretion can occur with ACE inhibitors. If you have these symptoms contact your doctor as soon as possible. hepatitis **Respiratory and heart:** cough, often described as dry and irritating, shortness of breath, discomfort on exertion changes in the rhythm or rate of the heartbeat, fast or irregular heartbeat difficulty breathing or wheezing eosinophilic pneumonia angina pectoris (a feeling of tightness, pressure or heaviness in the chest)

Less serious side effects	What to do
 changes in the rhythm or rate of the heartbeat swelling of hands, ankles or feet 	
Blood and investigations:	
 high levels in the blood of potassium, urea and/ or creatine, low sodium levels in the blood 	
 increase in some white blood cells 	
decreased blood sugar levels	
 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 	
Vascular disorders:	
hypotension	

 vasculitis flushing impaired peripheral circulation discolouration, numbness and pain in fingers or toes (Raynaud's
 impaired peripheral circulation discolouration, numbness and pain in fingers or
 circulation discolouration, numbness and pain in fingers or
numbness and pain in fingers or
pain in fingers or
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I TOES (Kavnaud S
phenomenon)
Musculoskeletal:
muscle cramps
• aching muscles,
muscle tenderness or
weakness, not caused
by exercise
• joint pain
Nervous system:
• headache, dizziness,
vertigo, pins and
needles • confusion or
confusion or hallucinations
Psychiatric:
mood disturbance, sleep disturbance, (difficulty)
disturbances (difficulty sleeping, abnormal

Less serious side effects	What to do
dreams), feeling sleepy or drowsy, fainting • depression	
Skin:	
 rash, pruritus (itching) excessive sweating increased sensitivity of the skin to sun, skin rash or inflammation of the skin often including blisters that weep and become crusted worsening of psoriasis 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 	
Eye, ear and nose:	
 vision disturbances tinnitus (persistent noise in the ears) runny or blocked nose, sneezing, facial pressure or pain nose bleeds 	

Less serious side effects	What to do
Reproductive system:	
erectile dysfunction	
General:	
 feeling tired, lethargic or weak 	
fever or high temperature	
generally feeling unwell	
• falls	
• chest pain	

Serious side effects

Serious side effects	What to do
 Respiratory and heart: difficulty in breathing a fast and irregular heartbeat myocardial infarction (heart attack) stroke Skin: 	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.
 purple spots with occasional blisters on the front of your arms and legs and/or around 	

Serious side effects	What to do
your neck and ears (a rare condition known as Stevens-Johnson Syndrome)	
 severe blisters, skin rash, itching, erythema multiforme or other allergic reactions. 	
 swelling of your extremities (limbs, hands or feet), lips, face, mouth, tongue or throat 	

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.

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.

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 PERISYL contains

Active ingredient	perindopril erbumine 2 mg, 4 mg or 8 mg
Other ingredients	 colloidal anhydrous silica sodium bicarbonate lactose microcrystalline cellulose magnesium stearate chlorophyllin-copper complex aluminium lake
Potential allergens	sugars as lactose

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

What PERISYL looks like

PERISYL 2 mg are 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. (AUST R 176516).

PERISYL 4 mg are green coloured mottled, capsule shaped, biconvex tablets debossed with "PT4" on one side of the tablet & "M" on the other side. Available in blister packs of 30. (AUST R 176518).

PERISYL 8 mg are 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. (AUST R 176517).

Who distributes PERISYL

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

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PERISYL® is a Viatris company trade mark

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