

# PERISYL<sup>®</sup> COMBI

## Consumer Medicine Information (CMI) summary

The [full CMI](#) 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 COMBI?

PERISYL COMBI contains the active ingredient perindopril erbumine and indapamide hemihydrate. PERISYL COMBI is used to treat high blood pressure. For more information, see Section [1. Why am I taking PERISYL COMBI?](#) in the full CMI.

### 2. What should I know before I take PERISYL COMBI?

Do not take if you have ever had an allergic reaction to perindopril erbumine, indapamide hemihydrate 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 COMBI?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with PERISYL COMBI 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 COMBI?

- Your doctor will select a dose when they prescribe PERISYL COMBI for you. The usual dose is one tablet once daily.
- Swallow your tablet with water, preferably in the morning.

More instructions can be found in Section [4. How do I take PERISYL COMBI?](#) in the full CMI.

### 5. What should I know while taking PERISYL COMBI?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking PERISYL COMBI.</li><li>• If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.</li><li>• 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.</li><li>• Tell your doctor immediately if you notice any serious side effects, especially severe nausea or vomiting or stomach pain.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take PERISYL COMBI to treat any other complaints unless your doctor tells you to.</li><li>• Do not give PERISYL COMBI to anyone else, even if they have the same condition as you.</li><li>• Do not stop taking PERISYL COMBI or change the dosage without checking with your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Take care when driving or operating machinery until you know how this medicine affects you.</li><li>• Dizziness or weakness due to low blood pressure may occur in certain patients. If you have any of these symptoms do not drive or operate machinery.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store in a cool, dry place below 25°C.</li><li>• Keep your tablets in the pack until it is time to take them.</li></ul>

For more information, see Section [5. What should I know while taking PERISYL COMBI?](#) in the full CMI.

### 6. Are there any side effects?

**Less serious side effects:** nausea, vomiting, diarrhoea, constipation, dry mouth, cough, low blood pressure, muscle spasms, muscle tenderness or weakness, headache, dizziness, vertigo, pins and needles, altered mood, sleep disorder, rash, nosebleeds, generally feeling unwell. **Serious side effects:** concentrated urine, chest pain, palpitations, bleeding or bruising more easily than normal, frequent infections, depression, anxiety, confusion, decrease in vision or pain in your eyes. **Very serious side effects:**, severe dizziness or fainting, difficulty breathing or wheezing, tightening of the chest, severe allergic reaction, swelling of your extremities, large blisters on skin. **This is not a complete list of side effects.** For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# PERISYL® COMBI

Active ingredient(s): *perindopril erbumine and indapamide hemihydrate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about taking PERISYL COMBI. **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 COMBI.**

**Where to find information in this leaflet:**

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

## 1. Why am I taking PERISYL COMBI?

PERISYL COMBI contains the active ingredient **perindopril erbumine and indapamide hemihydrate**. Perindopril belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors. Indapamide belongs to a group of medicines called diuretics (a type of "water" tablet).

You have been prescribed PERISYL COMBI for high blood pressure.

**PERISYL COMBI is used to treat high blood pressure.**

Everyone has blood pressure. This pressure helps to circulate blood all around the body. Your blood pressure may be different at different times of the day, depending on how busy or stressed you are. You have high blood pressure (also known as hypertension) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

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 COMBI helps to lower your blood pressure.

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

There is no evidence that PERISYL COMBI is addictive.

## 2. What should I know before I take PERISYL COMBI?

### Warnings

**Do not take PERISYL COMBI if:**

- you are allergic to perindopril, indapamide, 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 are allergic to sulfonamide (sulfa) antibiotics, or to thiazide diuretics (a type of 'fluid' or 'water' tablet).
- you are allergic to another angiotensin converting enzyme (ACE) inhibitor.
- 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:
  - o renal dialysis or haemofiltration using polyacrylonitrile membranes
  - o low-density lipoprotein (LDL) apheresis, a technique where LDL is 'filtered' out of a patient's 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 suffering from decreases in the amount, or absence of, urine produced by the kidney.
- you have narrowing of the main blood vessel leading from the heart and/or heart valve.
- you have low blood potassium.
- you have severe liver disease or suffer from a condition called hepatic encephalopathy (degenerative disease of the brain that occurs as a result of liver disease).
- you have experienced serious swelling of the face, tongue, lips or throat either suddenly or in response to another medicine in the past (a rare allergic condition known as angioedema).
- 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 subheading 'Tell Your Doctor Straight Away' and Section [3. What if I am taking other medicines?](#)).
- the packaging is damaged or shows signs of tampering, or the tablets do not look quite right.
- the expiry date (EXP) on the pack has passed.

**Tell your doctor straight away if you:**

- have a severe allergic reaction with swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema). This may occur at any time during treatment. If you develop such symptoms, you should stop taking PERISYL COMBI and see a doctor immediately (See additional information under Section [6. Are there any side effects?](#)).
- are undergoing desensitisation treatment, or have had an allergic reaction during previous desensitisation

treatment (e.g. treatments using bee, wasp or ant venom).

- are undergoing, or you are intending to undergo, treatments where your blood is treated outside of the body (also known as extracorporeal treatments).
- are undergoing anaesthesia and/or surgery.
- are undergoing a medical test that requires injection of an iodinated contrast agent (a substance that makes organs like the kidney or stomach visible on an X-ray).
- have recently suffered from diarrhoea or vomiting, or are dehydrated.
- are on a salt restricted diet or use salt substitutes which contain potassium.
- have an intolerance to some sugars as PERISYL COMBI contains lactose.
- are of African origin since you may have a higher risk of angioedema and this medicine is less effective in lowering your blood pressure.
- are taking lithium (used to treat mania or depression).
- are taking any of the following medicines used to treat high blood pressure:
  - o 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 sacubitril (available as fixed dose combination with another medicine valsartan), used to treat long-term heart failure
  - o aliskiren.
- have any other health problems, including:
  - o kidney disease or if you are on renal dialysis
  - o liver disease
  - o high or low levels of potassium, sodium, or other problems with salt balance
  - o diabetes
  - o gout
  - o heart disease
  - o hardening of the arteries
  - o hyperparathyroidism (overactive parathyroid gland)
  - o photosensitivity reactions (increased sensitivity of the skin to sun)
  - o systemic lupus erythematosus or scleroderma (a disease affecting the skin, joints and kidneys)
  - o abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism)
  - o if you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye or an increase of pressure in your eye and can happen within hours to a week of taking PERISYL COMBI. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.
  - o muscle disorders including muscle pain, tenderness, weakness or cramps.

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 [6. Are there any side effects?](#)

## Pregnancy and breastfeeding

**Do not take PERISYL COMBI if you are pregnant or trying to become pregnant.**

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

Tell your doctor straight away if you are pregnant or become pregnant while taking PERISYL COMBI, as it may cause serious harm to your unborn baby.

## For older people and children

Elderly people can generally use PERISYL COMBI safely. However, some older people have reduced kidney function - in which case additional care may be required.

PERISYL COMBI is not recommended for use in children and adolescents.

## 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 COMBI may change the effect of some medicines and some medicines may affect how well PERISYL COMBI works. You may need different amounts of your medication or to take different medicines.

**Some medicines may interfere with PERISYL COMBI and affect how it works. These include:**

- Some steroid medicines
- Diuretics (sometimes called 'fluid' or 'water' tablets because they increase the amount of urine passed each day, e.g. amiloride, spironolactone, triamterene)
- Medicines used for heart rhythm problems (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, flecainide)
- Some medications used to treat high blood pressure (including angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers), aliskiren (see Section [2. What should I know before I take PERISYL COMBI?](#))
- Some treatments where your blood is treated outside of the body, also known as extracorporeal treatments (see Section [2. What should I know before I take PERISYL COMBI?](#))
- Some antibiotic and medicines used to treat infections (e.g. trimethoprim, moxifloxacin)
- Medicines used to treat fungal disease [e.g. amphotericin B (amphotericin)] by injection, fluconazole)
- Tetracosactide (tetracosactrin) (to treat Crohn's disease)
- Some anti-inflammatory medicines (including high dose aspirin, ibuprofen) for pain relief
- Some anaesthetic medicines.

- Medicines used to treat mental illnesses such as some medicines for epilepsy, anxiety, schizophrenia and some other antidepressants (e.g. lithium, tricyclic antidepressants, antipsychotics drugs, neuroleptics such as: droperidol, haloperidol, chlorpromazine, trifluoperazine, amisulpride, sulpiride, psychoanaleptics).
- Antiparasitic medicines used to treat certain types of malaria (e.g. chloroquine).
- Pentamidine (a medicine used to treat certain types of pneumonia).
- Antihistamines used to treat allergic reactions, such as hay fever.
- Medicines used to treat nausea and vomiting (e.g. ondansetron, domperidone).
- Medicines used to treat gastrointestinal problems (e.g. cisapride, papaverine).
- Potassium-sparing diuretics (e.g. spironolactone, triamterene), 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)
- Medicines used to treat cancer (e.g. vandetanib, oxaliplatin) or to suppress the immune system (e.g. ciclosporin, tacrolimus).
- Non-steroidal anti-inflammatory drugs for pain relief (e.g. ibuprofen) or high doses of aspirin.
- Vasodilators including nitrates
- Medicines used to treat diabetes (e.g. metformin, gliptins and insulin)
- 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 affect the blood cells, such as allopurinol, procainamide
- Medicines which may increase the risk of angioedema (a severe allergic reaction) such as
  - o Mammalian target of rapamycin (mTOR) inhibitors used to avoid rejection of transplanted organs (e.g. temsirolimus, sirolimus, everolimus)
  - o Sacubitril (available as fixed dose combination with valsartan), used to treat long-term heart failure ( see Section [2. What should I know before I take PERISYL COMBI?](#)).
  - o gliptins used to treat diabetes (e.g. linagliptin, saxagliptin, sitagliptin, vildagliptin, alogliptin).
- Iodinated contrast agent used in certain medical tests
- Methadone (a medicine used to treat severe pain or opioid addiction)
- Digoxin or other cardiac glycosides (for the treatment of heart problems)
- Calcium supplements

- Stimulant laxatives (e.g. senna).
- Medicines used to treat bacterial infections (e.g. moxifloxacin, ciprofloxacin, clarithromycin)
- Allopurinol (a medicine used to treat gout).
- Cilostazol (used to treat cramp - like pain in the legs when you walk).

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

**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 COMBI.**

## 4. How do I take PERISYL COMBI?

### How much to take

- Follow all directions given to you by your doctor or pharmacist carefully.
- If you do not understand the instructions on the label, ask your doctor or pharmacist for help.
- Your doctor will select a dose when they prescribe PERISYL COMBI for you. The usual dose is one tablet once daily.

### When to take PERISYL COMBI

- Swallow your tablet with water, preferably in the morning.

### How long to take PERISYL COMBI for

- PERISYL COMBI can help to control your blood pressure but cannot cure this condition.
- PERISYL COMBI treatment is usually for life - so you should keep taking the tablets regularly unless advised otherwise by your doctor.

### If you forget to take PERISYL COMBI

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

If your next usual dose is less than 6 hours away, just leave out the dose that you missed. Take the next dose at the usual time and continue as normal.

If your next dose is more than 6 hours away, take the dose you have missed as soon as you realise. Then take the next dose at the usual time and continue as normal.

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

### If you take too much PERISYL COMBI

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

**You should immediately:**

- phone the Poisons Information Centre (Australia telephone 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.**

Taking too much PERISYL COMBI (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. If this happens, lying down with the legs elevated can help.**

Other effects like nausea, vomiting, cramps, sleepiness, confusion, changes in the amount of urine produced by the kidney are possible. You may require urgent medical attention.

## 5. What should I know while taking PERISYL COMBI?

### Things you should do

- Take PERISYL COMBI 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 COMBI.
- 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.

### Call your doctor straight away if you:

- have excessive vomiting or diarrhea while taking PERISYL COMBI.

### Things you should not do

- Do not take PERISYL COMBI to treat any other complaints unless your doctor tells you to.
- Do not give PERISYL COMBI to anyone else, even if they have the same condition as you.
- Do not stop taking PERISYL COMBI or change the dosage without checking with your doctor.

### Driving or using machines

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

You may feel light-headed or dizzy when you begin to take PERISYL COMBI. This is because your blood pressure is falling. If you have these symptoms when standing up or getting out of bed then getting up more slowly can help. This allows your body to get used to the change in position and blood pressure.

If you have these symptoms and they don't get better in a short time then talk to your doctor.

### Looking after your medicine

- Keep your tablets in the pack until it is time to take them. If you take them out of the pack they may not keep well.
- Store below 25°C.

Follow the instructions on 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.

**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.

### Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

## 6. Are there any side effects?

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
<b>Gastrointestinal</b> <ul style="list-style-type: none"><li>• Nausea, vomiting, taste disturbances, indigestion, diarrhoea, constipation, stomach pain or discomfort</li><li>• Gastrointestinal inflammation</li><li>• Decreased appetite</li></ul> <b>Mouth</b> <ul style="list-style-type: none"><li>• Dry mouth</li></ul> <b>Kidney or liver related</b> <ul style="list-style-type: none"><li>• Abnormal kidney function</li><li>• Abnormal liver function</li><li>• Polyuria - increased urination</li><li>• Problems with production or passing of urine</li><li>• Elevation of bilirubin levels in the blood, increases in liver enzymes.</li></ul> <b>Respiratory and heart</b> <ul style="list-style-type: none"><li>• Cough, often described as dry and irritating, shortness of breath, discomfort on exertion</li><li>• Bronchitis (inflammation of the airways leading into your lungs), upper respiratory tract infection</li></ul> <b>Blood and investigations</b> <ul style="list-style-type: none"><li>• Low sodium (salt) levels in the blood that may lead to dehydration and low blood pressure</li><li>• Low potassium in the blood</li></ul>	<b>Speak to your doctor, pharmacist or nurse if you have any of these less serious side effects, some of which are usually only identified after a blood test.</b>

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>High levels in the blood of potassium, urea and/or creatine</li> <li>Low chloride in the blood, low magnesium in the blood</li> <li>Decreased blood sugar levels</li> <li>Increase in some white blood cells</li> <li>Elevated calcium levels in the blood</li> <li>Illnesses resulting from a lack of red blood cells</li> <li>Blood glucose increased</li> <li>Blood uric acid increased</li> </ul> <p><b>Vascular disorders</b></p> <ul style="list-style-type: none"> <li>Vasculitis (inflammation of blood cells)</li> <li>Low blood pressure (and related effects), flushing, impaired peripheral circulation, vasculitis</li> <li>Impaired peripheral circulation</li> <li>Discolouration, numbness and pain in fingers or toes (Raynaud's phenomenon)</li> </ul> <p><b>Musculoskeletal</b></p> <ul style="list-style-type: none"> <li>Muscle spasms</li> <li>Muscle tenderness or weakness</li> <li>Back pain</li> <li>Aching muscles, not caused by exercise, Joint pain</li> </ul> <p><b>Nervous system</b></p> <ul style="list-style-type: none"> <li>Headache, dizziness, vertigo, pins and needles</li> <li>Altered mood, sleep disorder (difficulty sleeping, abnormal dreams), feeling sleepy or drowsy, fainting</li> </ul> <p><b>Skin</b></p> <ul style="list-style-type: none"> <li>Rash, pruritus (itching), red raised skin rash</li> <li>Hypersensitivity reactions, mainly skin reactions, in patients with allergies and asthmatic reactions</li> <li>Excessive sweating</li> <li>Increased sensitivity of the skin to sun, skin rash or inflammation of the skin often including blisters that weep and become crusted</li> <li>Worsening of psoriasis</li> </ul> <p><b>Eye, ear and nose</b></p> <ul style="list-style-type: none"> <li>Nosebleeds</li> <li>Tinnitus (persistent noise in the ears), vertigo, vision impairment</li> <li>Myopia, blurred vision</li> </ul>	

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>Runny or blocked nose, sneezing, facial pressure or pain</li> </ul> <p><b>Reproductive system</b></p> <ul style="list-style-type: none"> <li>Erectile dysfunction, libido disorder</li> </ul> <p><b>General</b></p> <ul style="list-style-type: none"> <li>Feeling tired or weak</li> <li>Fever or high temperature</li> <li>Generally feeling unwell or lethargic</li> </ul>	

### Serious side effects

Serious side effects	What to do
<p><b>Kidney or liver related</b></p> <ul style="list-style-type: none"> <li>Kidney failure</li> <li>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. <b>If you have these symptoms contact your doctor as soon as possible.</b></li> <li>Cystitis - an infection of the bladder</li> </ul> <p><b>Respiratory and heart</b></p> <ul style="list-style-type: none"> <li>Eosinophilic pneumonia</li> <li>Chest pain</li> <li>Fast heartbeat</li> <li>Palpitations (awareness of your heartbeat)</li> <li>Abnormal ECG heart tracing</li> <li>Changes in the rhythm or rate of the heartbeat</li> </ul> <p><b>Vascular conditions</b></p> <ul style="list-style-type: none"> <li>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)</li> </ul> <p><b>Nervous system</b></p> <ul style="list-style-type: none"> <li>Depression</li> <li>Anxiety</li> <li>Syncope - fainting not associated with seizures or trauma</li> <li>Confusion, or hallucinations</li> </ul> <p><b>Skin</b></p>	<p><b>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.</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>Blistering and rashes on the skin (Pemphigoid) - usually affecting older people</li> </ul> <p><b>Eye, ear and nose</b></p> <ul style="list-style-type: none"> <li>Decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye or acute angle - closure glaucoma)</li> </ul> <p><b>Autoimmune</b></p> <ul style="list-style-type: none"> <li>Worsening of pre-existing Lupus Erythematosus</li> </ul> <p><b>Autoimmune</b></p> <ul style="list-style-type: none"> <li>Falls</li> </ul>	

### Very serious side effects

Very serious side effects	What to do
<p><b>Vascular</b></p> <ul style="list-style-type: none"> <li>Dizziness becoming severe or fainting induced by low blood pressure</li> </ul> <p><b>Respiratory or heart</b></p> <ul style="list-style-type: none"> <li>Difficulty breathing or wheezing, tightening of the chest</li> <li>Stroke (signs include weakness of arms or legs or problems speaking)</li> <li>Heart disorders such as a fast and irregular heartbeat, heart attack, angina pectoris (a feeling of tightness, pressure or heaviness in the chest)</li> <li>Life-threatening irregular heartbeat (Torsades de pointes)</li> </ul> <p><b>Allergic reaction</b></p> <ul style="list-style-type: none"> <li>Angioedema (a severe allergic reaction) has been reported in patients treated with ACE inhibitors, including PERISYL COMBI. 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</li> </ul>	<p><b>Stop taking PERISYL COMBI and call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</b></p>

Very serious side effects	What to do
<p>feet), lips, face, mouth, tongue or throat.</p> <p><b>Skin</b></p> <ul style="list-style-type: none"> <li>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).</li> <li>Painful red areas, developing large blisters and peeling of layers of skin. This is accompanied by fever and chills (a condition known as Toxic Epidermal Necrolysis or TEN).</li> <li>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 (a condition known as Erythema Multiforme).</li> </ul> <p><b>Pancreatic or liver related</b></p> <ul style="list-style-type: none"> <li>Inflammation of the pancreas (Pancreatitis).</li> <li>Liver disease (Hepatitis) characterised by yellowing of the skin or eyes (jaundice).</li> </ul> <p><b>Nervous system</b></p> <ul style="list-style-type: none"> <li>Disease of the brain caused by liver illness (Hepatic encephalopathy).</li> </ul> <p><b>Musculoskeletal</b></p> <ul style="list-style-type: none"> <li>Muscle spasms, tenderness, pain or weakness and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown.</li> </ul>	

**Tell your doctor, nurse 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.

Changes may occur in your laboratory parameters (blood tests) and your doctor may need to give you blood tests to check your condition. The following changes in laboratory tests may occur: low potassium in the blood, low sodium in the blood (that may lead to dehydration and low blood pressure), increase in uric acid (a substance which may cause or worsen gout), increase in blood glucose levels in diabetic patients, increased levels of liver enzymes.

If you are about to have any blood tests, tell your doctor that you are taking PERISYL COMBI. It may interfere with the results of some tests. Your doctor may do some tests



from time to time to make sure the medicine is working and to prevent unwanted side effects.

### 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](http://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 COMBI contains

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"><li>• 4 mg of perindopril erbumine</li><li>• 1.25 mg of indapamide hemihydrate</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• colloidal anhydrous silica</li><li>• sodium bicarbonate</li><li>• lactose</li><li>• microcrystalline cellulose</li><li>• magnesium stearate</li></ul>
<b>Potential allergens</b>	<ul style="list-style-type: none"><li>• lactose</li></ul>

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

### What PERISYL COMBI looks like

PERISYL COMBI is a white, capsule shaped, biconvex tablet debossed with "PTI" on one side of the tablet and "M2" on the other side. (AUST R 179752).

Available in blister packs of 30 tablets.

### Who distributes PERISYL COMBI

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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PERISYL® is a Viatris company trade mark

PERISYL COMBI\_cmi\Nov25/00