

PERISYL[®] COMBI

perindopril erbumine and indapamide hemihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PERISYL COMBI.

It does not contain all the available information. Reading this leaflet 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 PERISYL COMBI 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 COMBI is

The name of your medicine is PERISYL COMBI. The medicine contains the active ingredients 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).

What PERISYL COMBI is used for

You have been prescribed PERISYL COMBI for high blood pressure.

PERISYL COMBI is available only with a doctor's prescription.

There is no evidence that PERISYL COMBI is addictive.

Why PERISYL COMBI is used for 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.

Before you take PERISYL COMBI

There are some people who should not take PERISYL COMBI. Please read the lists below. If you think any

of these situations apply to you, or you have any questions, please consult your doctor or pharmacist.

Do not take PERISYL COMBI if:

- **You are allergic to perindopril, indapamide, or any of the other ingredients of PERISYL COMBI listed at the end of this leaflet.**
- **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 are pregnant or trying 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 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.**
- **If you have low blood potassium.**
- **If 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 'Tell Your Doctor Straight Away' and 'Taking Other Medicines' sections).**
- **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 are pregnant or become pregnant while taking PERISYL COMBI, as it may cause serious harm to your unborn baby.
- 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 also 'SIDE EFFECTS' section).

- 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 undergoing anaesthesia and/or surgery.
- You 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)
- 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 COMBI contains lactose.
- You are of African origin since you may have a higher risk of angioedema and this medicine is less effective in lowering your blood pressure.
- 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

- sacubitril (available as fixed dose combination with another medicine valsartan), used to treat long-term heart failure
- aliskiren.
- You have any other health problems, including:
 - Kidney disease or if you are on renal dialysis
 - Liver disease
 - High or low levels of potassium, sodium, or other problems with salt balance
 - Diabetes
 - Gout
 - Heart disease
 - Hardening of the arteries
 - Hyperparathyroidism (overactive parathyroid gland)
 - Photosensitivity reactions (increased sensitivity of the skin to sun)
 - Systemic lupus erythematosus or scleroderma (a disease affecting the skin, joints and kidneys)
 - Abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism)
 - 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.
 - Muscle disorders including muscle pain, tenderness, weakness or cramps.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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. The medicines that may interact with PERISYL COMBI include the following:

- 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 also 'Do Not Take PERISYL COMBI If' and 'Tell Your Doctor Straight Away' sections)
- Some treatments where your blood is treated outside of the body, also known as extracorporeal treatments (see also 'Do Not Take PERISYL COMBI If' and 'Tell Your Doctor Straight Away' sections)
- 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, psychoanaesthetics).
- 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
 - 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 COMBI If' and 'Tell Your Doctor Straight Away' sections).
 - 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.

For older people or 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.

How to take PERISYL COMBI

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.

Swallow your tablet with water, preferably in the morning.

How long to take it

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 it

- 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 try to make up for missed doses by taking more than one dose at a time.

If you take too much (overdose)

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.

If you think that you or anyone else may have taken too much PERISYL COMBI then act immediately:

Immediately telephone your doctor or the Poisons Information Centre (Australia telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are taking PERISYL COMBI

Things you must 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.

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

Things you must not do

Do not take PERISYL COMBI to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or change the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery 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.

Side effects

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

This medicine helps most people with high blood pressure, but it may have unwanted side effects in some people.

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

PERISYL COMBI helps most people with high blood pressure, but it may sometimes have unwanted side effects in a few people. While these side effects when they occur are usually mild they can be serious.

Stop taking PERISYL COMBI and see a doctor immediately, if you experience any of the following side effects that can be serious:

- Dizziness becoming severe or fainting induced by low blood pressure
- Difficulty breathing or wheezing, tightening of the chest. (Uncommon)
- 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 feet), lips, face, mouth, tongue or throat. (Uncommon)
- 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). (Very rare)
- 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). (Very rare)
- 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). (Very rare)
- Stroke (signs include weakness of arms or legs or problems speaking). (Very rare)

- Heart disorders such as a fast and irregular heartbeat, heart attack, angina pectoris (a feeling of tightness, pressure or heaviness in the chest). (Very rare)
- Inflammation of the pancreas (Pancreatitis). (Very rare)
- Liver disease (Hepatitis) characterised by yellowing of the skin or eyes (jaundice). (Very rare)
- Life-threatening irregular heartbeat (Torsades de pointes). (Frequency not known)
- Disease of the brain caused by liver illness (Hepatic encephalopathy). (Frequency not known)
- 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. (Frequency not known)

The above side effects are categorised into the following frequencies:

Common - may affect up to 1 in 10 people

Uncommon - may affect up to 1 in 100 people

Rare - may affect up to 1 in 1,000 people

Very rare - may affect up to 1 in 10,000 people

Not known - frequency cannot be estimated from the data available

Talk to your doctor or pharmacist or nurse if you notice any of the following side effects, some of which are usually only identified after blood tests:

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
- Nosebleeds
- Headache, dizziness, vertigo, pins and needles
- Feeling tired or weak

- Tinnitus (persistent noise in the ears), vertigo, vision impairment
- Low blood pressure (and related effects), flushing, impaired peripheral circulation, vasculitis
- Low potassium in the blood
- Nausea, vomiting, taste disturbances, indigestion, diarrhoea, constipation, stomach pain or discomfort
- Dry mouth
- Decreased appetite
- Muscle spasms
- Muscle tenderness or weakness
- Rash, pruritus (itching), red raised skin rash
- Hypersensitivity reactions, mainly skin reactions, in patients with allergies and asthmatic reactions.

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 (salt) levels in the blood that may lead to dehydration and low blood pressure
- Altered mood, sleep disorder (difficulty sleeping, abnormal dreams), feeling sleepy or drowsy, fainting.
- Anxiety
- Bronchitis, upper respiratory tract infection
- Back pain
- Gastrointestinal inflammation
- Excessive sweating.
- Increased sensitivity of the skin to sun, skin rash or inflammation of the skin often including blisters that weep and become crusted
- Pemphigoid - a skin disease usually affecting older people
- Increase in some white blood cells
- Erectile dysfunction, libido disorder

- Fever or high temperature
- Chest pain
- Fast heartbeat
- Palpitations (awareness of your heartbeat)
- Abnormal ECG heart tracing
- Abnormal kidney function
- Polyuria - increased urination
- Cystitis - an infection of the bladder
- Decreased blood sugar levels
- Worsening of pre-existing Lupus Erythematosus
- Aching muscles, not caused by exercise, Joint pain
- Generally feeling unwell or lethargic
- Falls
- Vasculitis (inflammation of blood cells)
- Impaired peripheral circulation
- Syncope - fainting not associated with seizures or trauma.
- Kidney failure

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

- Low chloride in the blood, low magnesium in the blood
- Elevation of bilirubin levels in the blood, increases in liver enzymes
- Elevated calcium levels in the blood
- Worsening of psoriasis
- 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:

- Abnormal liver function
- Eosinophilic pneumonia

- Runny or blocked nose, sneezing, facial pressure or pain
- 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
- Changes in the rhythm or rate of the heartbeat
- Confusion, or hallucinations.

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

- Myopia, blurred vision
- Blood glucose increased
- Blood uric acid increased
- Discolouration, numbness and pain in fingers or toes (Raynaud's phenomenon)
- 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)

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

Most of these side effects are mild when they occur. 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.

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.

After taking PERISYL COMBI

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 COMBI 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 COMBI 4/1.25: White, capsule shaped, biconvex tablet debossed with "PTI" on one side of the tablet and "M2" on the other side. Available in blister packs of 30 tablets.

Ingredients

PERISYL COMBI 4/1.25 tablet contains 4 mg of perindopril erbumine and 1.25 mg of indapamide

hemihydrate as the active ingredients.

The tablets also contain the following inactive ingredients:

- colloidal anhydrous silica
- sodium bicarbonate
- lactose
- microcrystalline cellulose
- magnesium stearate

Supplier

PERISYL COMBI 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

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Australian registration number:

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