

APO-Perindopril/Indapamide 4/1.25 Tablets

Contains the active ingredients perindopril erbumine and indapamide hemihydrate

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about this medicine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine is used for

The name of your medicine is APO-Perindopril/Indapamide 4/1.25 tablets. It contains the active ingredients perindopril and indapamide, which are used to treat high blood pressure (also known as hypertension).

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 (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.

Perindopril/indapamide 4/1.25 helps to lower your blood pressure

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

Your doctor may have prescribed this medicine for another reason.

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

There is no evidence that this medicine is addictive.

Use in older people or children

Elderly people can generally use Perindopril/Indapamide 4/1.25 safely. However, some older people have reduced kidney function - in which case additional care may be required.

Perindopril/Indapamide 4/1.25 is not recommended for use in children and adolescents.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicine containing perindopril or indapamide
- sulphonamide (sulpha) antibiotics, thiazide diuretics (a type of "fluid" or "water" tablet)
- any other angiotensin converting enzyme (ACE) inhibitor
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing

- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if 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).

Do not take this medicine if you are intolerant or allergic to lactose.

This medicine contains lactose.

Do not take this medicine if you have or have had any of the following medical conditions:

- severe heart failure which is not being treated
- low potassium levels (hypokalaemia)
- severe liver problems or hepatic encephalopathy (degenerative disease of the brain that occurs as a result of liver disease)
- trouble urinating (i.e. little or no urine)
- severe kidney problems or if you are on dialysis
- renal artery stenosis (a problem with the blood vessels to one or both kidneys)
- narrowing of the main blood vessel leading from the heart and/or heart valve.

Do not take this medicine if 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, 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 sulphate.

Do not take this medicine if you are taking other medicines which have the possible side effect of a heart problem called torsades de pointes, including:

- some medicines used to treat abnormal heart rhythms (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol or flecainide)
- some medicines used to treat mental illnesses (e.g. trifluoperazine, amisulpride, sulpiride, droperidol or haloperidol)
- other medicines such as diphemanil, erythromycin IV, pentamidine or moxifloxacin
- sacubitril/valsartan combinations, 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

Do not take this medicine if you are treated with a blood pressure lowering medicine containing aliskiren and have diabetes or impaired kidney function.

Do not take this medicine if you are pregnant or trying to become pregnant.

Perindopril/indapamide 4/1.25 may affect your developing baby if you take it during pregnancy.

Do not take this medicine if you are breastfeeding or intend to breast-feed.

Perindopril/indapamide 4/1.25 may pass into human breast milk.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney disease or you are on renal dialysis
- liver disease
- heart or blood vessel disease
- hyperparathyroidism (overactive parathyroid gland)
- photosensitivity reactions (increased sensitivity of the skin to sun)
- diabetes
- gout
- systemic lupus erythematosus (a disease affecting the skin, joints and kidneys)
- high or low levels of potassium, low levels of sodium or chlorine, or high levels of uric acid
- you are on a salt restricted diet or use salt substitutes which contain potassium
- 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 a medical test that requires injection of an iodinated contrast agent (a substance that makes organs like kidney or stomach visible on an X-ray)
- you have recently suffered from diarrhoea or vomiting or are dehydrated
- you are undergoing de-sensitisation treatment or have had an allergic reaction during previous desensitisation treatment (e.g. treatments using bee, wasp or ant venom)
- abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism)
- muscle disorders including muscle pain, tenderness, weakness or cramps
- 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 perindopril/indapamide 4/1.25. 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.
- 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 undergoing anaesthesia and/or surgery.
- 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.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Do not take this medicine whilst pregnant or breastfeeding.

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.

Some medicines may interact with perindopril/indapamide 4/1.25. These include:

- some medicines used to treat high blood pressure (including angiotensin receptor blockers), aliskiren, diuretics (sometimes called "fluid" or "water" tablets because they increase the amount of urine passed each day, e.g. amiloride, spironolactone, triamterene) or medicines used to treat heart failure (e.g. sacubitril/valsartan or digoxin or other cardiac glycosides)
- some anti-inflammatory medicines (including high dose aspirin and ibuprofen) for pain relief

It is especially important to tell your doctor when taking blood pressure, water and/or heart tablets together with anti-inflammatory medicines.

- some medicines used to treat gout (e.g. allopurinol)
- some medicines used to treat cancer (e.g. vandetanib, oxaliplatin or anagrelide), or to suppress the immune system, such as after organ transplants (e.g. ciclosporin, tacrolimus)
- baclofen, a muscle relaxant
- some antibiotics used to treat infections (e.g. trimethoprim, ciprofloxacin or moxifloxacin)
- some anti-fungal medications used to treat fungal infections (e.g. fluconazole or amphotericin B by injection)
- medicines such as lithium and tricyclic antidepressants (e.g. imipramine, citalopram or escitalopram) for treating depression and mood disorders
- medicines used for treating psychiatric disorders
- donepezil, used in Alzheimer's disease
- medicines which increase blood potassium levels, such as potassium-sparing diuretics, potassium tablets, salt substitutes containing potassium, or other medicines which can increase potassium in your body (e.g. 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 which decrease blood potassium levels such as steroids, tetracosactide and certain types of laxatives (e.g. senna)
- antiparasitic medicines used to treat certain types of malaria (e.g. chloroquine).
- pentamidine, 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 or domperidone)
- medicines which have the possible side effect of a heart problem called torsades de pointes, including: some medicines used to treat abnormal heart rhythms (e.g. disopyramide, amiodarone, sotalol or flecainide); some medicines used to treat mental illnesses (e.g. trifluoperazine, amisulpride, sulpiride, droperidol, haloperidol); other medicines such as diphemanil, erythromycin IV, pentamidine, moxifloxacin
- metformin, insulin or gliptins (e.g. sitagliptin, linagliptin, saxagliptin, vildagliptin, alogliptin), medicines used to treat diabetes
- 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)
- calcium supplements
- injections containing iodine used to diagnose certain medical conditions
- alcohol or strong painkillers (e.g. methadone)
- medicines which make your heartbeat faster or increase your blood pressure, such as decongestants (in cold & flu remedies)
- medicines used during operations (e.g. anaesthetics)
- cilostazol (used to treat cramp-like pain in the legs when you walk)
- 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 - gliptins used to treat diabetes (e.g. linagliptin, saxagliptin, sitagliptin, vildagliptin, alogliptin).
- Vasodilators including nitrates

These medicines may be affected by perindopril/indapamide 4/1.25 or may affect how well it works.

If you are taking any of these, you may need a different dose, or you may need to take different medicines.

Other medicines not listed above may also interact with perindopril/indapamide 4/1.25.

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

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the directions, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

How to take it

Swallow your tablet(s) with a glass of water.

Do not crush or chew the tablets.

When to take it

Take it at about the same time each day, preferably in the morning before breakfast.

Taking it at the same time each day will have the best effect and will also help you remember when to take it.

How long to take it for

Perindopril/indapamide 4/1.25 can help to control your blood pressure or heart failure but cannot cure these conditions.

Perindopril/indapamide 4/1.25 treatment is usually for life, so you should keep taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

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

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 missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much perindopril/indapamide 4/1.25, your blood pressure may drop (hypotension) or you may be sick, feel confused, or have kidney problems or changes in the salt and water content of your body or muscle cramps.

While you are taking this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

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

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

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 immediately if you notice any serious side effects, especially severe nausea or vomiting or stomach pain.

Things you must not do

Do not take this medicine 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 when driving or operating machinery until you know how this medicine affects you.

You may feel light-headed or dizzy when you begin to take this medicine. 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 do not get better in a short time, then talk to your doctor.

Perindopril/indapamide 4/1.25 contains a drug substance which may give a positive result in doping tests.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are taking perindopril/indapamide 4/1.25 or if you have any questions or concerns.

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

Perindopril/indapamide 4/1.25 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 perindopril/indapamide 4/1.25 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 perindopril/indapamide 4/1.25. 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)

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.
- Nose bleeds.
- Headache, dizziness, vertigo, pins and needles.
- Feeling tired or weak.
- Tinnitus (persistent noise in the ears), vertigo.
- Low blood pressure (and related effects), flushing, impaired peripheral circulation, vasculitis.
- Low potassium in the blood.
- Blurred or changed vision, short sightedness (myopia).
- 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).
- 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 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 heartbeat.
- Confusion or hallucinations.

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

- Blood glucose increased.
- Blood uric acid increased.
- Discolouration, numbness and pain in the 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.

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.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a windowsill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Perindopril/ Indapamide 4/1.25 tablets looks like

Perindopril/ Indapamide 4/1.25 tablets:

White, capsule-shaped, biconvex tablets engraved "4/1.25" on one side and "APO" on the other side.

AUST R 127122.

Available in blister packs of 30 tablets.

Ingredients

Each tablet contains 4 mg of Perindopril erbumine and 1.25 mg indapamide hemihydrate as the active ingredients.

It also contains the following inactive ingredients:

- lactose
- magnesium stearate.

This medicine is free from gluten, sucrose, tartrazine and other azo dyes.

Sponsor

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Web: www.arrotex.com.au

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