

GenRx 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

Read this leaflet carefully before taking your medicine.

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

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is GenRx Perindopril/ Indapamide 4/1.25 tablets. It contains the active ingredients perindopril and indapamide.

It is used to treat:

- high blood pressure (also known as hypertension).

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.

How it works

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 helps to lower your blood pressure

There is no evidence that this medicine is addictive.

Use in children

There is not enough information to recommend the use of this medicine in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have or have had any of the following:**
 - severe heart failure which is not being treated
 - low potassium levels (hypokalaemia)
 - severe liver problems
 - 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)
 - hepatic encephalopathy.
- **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. disopyramide, amiodarone, sotalol)
 - some medicines used to treat

mental illnesses (e.g. trifluoperazine, amisulpride, sulphiride, droperidol, haloperidol);

- other medicines such as diphemanil, erythromycin IV, pentamidine, moxifloxacin

- **You undergo renal dialysis using polyacrylonitrile membranes.**
- **You are treated with a blood pressure lowering medicine containing aliskiren and have diabetes or impaired kidney function**
- **You are pregnant or trying to become pregnant.**
Perindopril/indapamide may affect your developing baby if you take it during pregnancy.
- **You are breastfeeding or intend to breast-feed.**
Perindopril/indapamide may pass into human breast milk.
- **You have experienced 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 angio-oedema).**
- **You are intolerant or allergic to lactose. This medicine contains lactose.**
- **You are hypersensitive to, or have had an allergic reaction to, perindopril, indapamide, any of the ingredients listed at the end of this leaflet, sulphonamide (sulpha) antibiotics, thiazide diuretics (a type of "fluid" or "water" tablet), or any other angiotensin converting enzyme (ACE) inhibitor.**
Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.
If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor

immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - kidney disease
 - liver disease
 - heart or blood vessel disease
 - 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. If you have a salt imbalance you may feel thirsty, weak, drowsy, restless, sick, or have weak or cramped muscles, or have changes in your heart rate or rhythm. You may also have gout due to high uric acid levels
 - you have, or have had an allergic reaction during previous, low-density lipoprotein (LDL) apheresis, a technique where LDL is 'filtered' out of a patient's blood, using dextran sulphate
 - you have recently suffered from diarrhoea or vomiting
 - you are undergoing desensitisation treatment or have had an allergic reaction during previous desensitization treatment (e.g. treatments using bee, wasp or ant venom).
3. You are currently pregnant or you plan to become pregnant. Do not

take this medicine whilst pregnant.

4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

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

- Some medicines used to treat high blood pressure (including angiotensin receptor blockers), aliskiren, diuretics (sometimes called "fluid" or "water" tablets).
- some anti-inflammatory drugs (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 drugs.
- some drugs used to treat gout (e.g. allopurinol)
- some drugs used to treat cancer or to suppress the immune system (such as after organ transplants, e.g. cyclosporin)
- baclofen, a muscle relaxant
- some antibiotics used to treat infections
- medicines such as lithium and tricyclic antidepressants (e.g. imipramine) for treating depression and mood disorders
- medicines used for treating psychiatric disorders
- medicines which increase blood potassium levels, such as potassium-sparing diuretics, sources of potassium, like potassium tablets and salt substitutes containing potassium

- medicines which decrease blood potassium levels such as steroids, tetracosactide and certain types of laxative
- 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); some medicines used to treat mental illnesses (e.g. trifluoperazine, amisulpride, sulphiride, droperidol, haloperidol); other medicines such as diphemanil, erythromycin IV, pentamidine, moxifloxacin (see also 'When you must not take it').
- gliptins such as sitagliptan, a medicine used to lower blood sugar for diabetics
- medicines used to treat diabetes (tablets and insulin)
- gold injections used for treating arthritis
- calcium supplements
- injections containing iodine used to diagnose certain medical conditions
- strong painkillers
- alcohol
- medicines which make your heart beat faster or your blood pressure go up, such as decongestants (in cold remedies) or adrenaline
- medicines used during operations (e.g. anaesthetics).

These medicines may be affected by perindopril/indapamide 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.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

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.

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

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

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

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 (see 'Possible side effects').

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first 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 don't get better in a short time then talk to your doctor.

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

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are

taking perindopril/indapamide or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- a dry cough
- headache, dizziness, drowsiness, giddiness, numbness, tingling or pins and needles
- tinnitus (pain or ringing in the ears), problems with your eyesight
- hypotension (low blood pressure), palpitations, poor circulation in your hands and feet
- dry mouth, strange taste sensations, loss of appetite, flushing, constipation, diarrhoea
- feeling tired or weak or as if you have less energy
- feeling uncomfortable after eating, indigestion, feeling or being sick,
- rash, itching, pimples on the skin
- nose bleed, blocked nose
- muscle cramps, weak legs
- back or joint pain
- altered mood, problems when sleeping or getting to sleep, or strange dreams.

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects and you may need medical attention:

- sweating
- feeling depressed, anxious, confused or hearing or seeing things that are not there
- sexual problems
- kidney problems (i.e. cystitis, cloudy urine or problems urinating or urinating too much)
- sunburn following only a small exposure to the sun; fine, broken blood vessels below the skin, skin reaction which makes the skin look scalded.

- infections such as chest or throat infections, fever, severe chills or mouth ulcers
- itching blood vessels.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- 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).
- severe blisters, widespread skin rash, itching, skin reaction which makes the skin look scalded, or other skin reactions
- a fast, slow or irregular heartbeat
- angina or chest pain, loss of consciousness
- sudden weakness or numbness of the face, arms or legs, especially on one side, slurred speech
- liver problems, yellow skin or eyes
- not passing any urine
- feeling breathless or having problems breathing, chest infection such as bronchitis or pneumonia
- severe pains in the stomach or upper stomach
- feeling or being very sick.

Other side effects not listed above may occur in some patients.

Tell your doctor if you notice anything that is making you feel unwell.

Allergic reactions

If you think you are having an allergic reaction to perindopril/indapamide, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

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 window sill 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 GenRx Perindopril/ Indapamide 4/1.25 tablets looks like

GenRx Perindopril/ Indapamide 4/1.25 tablets:
White, capsule-shaped, biconvex

tablets, engraved "4/1.25" on one side and "APO" on the other side.

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:

- anhydrous lactose
- magnesium stearate.

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

Australian Registration Numbers

GenRx Perindopril/ Indapamide 4/1.25 tablets:
Blister packs of 30
AUST R 127119.

Sponsor

Apotex Pty Ltd
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