

PERINDOSYL

(Perindopril tert-butylamine 4 mg)

Consumer Medication Information Leaflet (RiMUP)

WHAT IS IN THIS LEAFLET:

1. What is PERINDOSYL used for
2. How PERINDOSYL works
3. Before you take PERINDOSYL
4. How to take PERINDOSYL
5. While you are using PERINDOSYL
6. Side effects
7. Storage and disposal of PERINDOSYL
8. Product description
9. Manufacturer & Product Registration Holder
10. Date of revision

WHAT IS PERINDOSYL USED FOR

PERINDOSYL is used to treat:

- high blood pressure (hypertension)
- heart failure (a condition where the heart is unable to pump enough blood to meet the body's needs);
- to reduce the risk of cardiac events, such as heart attack, in patients with stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) and who have already had a heart attack and/or an operation to improve the blood supply to the heart by widening the vessels that supply it.

HOW PERINDOSYL WORKS

Perindopril belongs to a class of medicines called ACE inhibitors. These work by widening the blood vessels, which makes it easier for your heart to pump blood through them.

BEFORE YOU USE PERINDOSYL

- When you must not use it

- if you are allergic (hypersensitive) to Perindopril or any of the other ingredients in the tablet or any other ACE inhibitor;
- if you have had symptoms such as wheezing, swelling of the face, tongue or throat, intense itching, skin rashes, fainting or dizziness with previous ACE inhibitor treatment or have had these symptoms in any other circumstances (this condition is called angioedema);
- if you have hereditary tendency to tissue swelling of unknown origin (hereditary or idiopathic angioedema);
- if you are pregnant;
- if you are taking aliskiren and have Type 2 diabetes;
- if you are taking concomitant medicine (sacubitril/valsartan);
- if you are having extracorporeal treatments;
- if you have significant kidney artery narrowing

If you think any of the above situations applies to you, do not take the tablets. Consult your doctor and take his/her advice.

- Before you start to use it

Take special care with PERINDOSYL.

You should check with your doctor BEFORE taking PERINDOSYL if you:

- are in risk of an excessive fall in the blood pressure. This may be the case, among others, if you suffer from heart failure, impaired renal function or disorders in the salt and fluid balance, e.g. because you take diuretics (medicines that increase urine production) or keep on low-salt diet or as a consequence of vomiting or diarrhea
- have aortic stenosis (narrowing of the main blood vessel leading from the heart), mitral valve stenosis (narrowing of heart's mitral valve), hypertrophic cardiomyopathy (cardiac muscle disease) or renal artery stenosis (narrowing of the artery supplying the kidney with blood)
- have kidney problem
- you are receiving dialysis
- have hypersensitivity reactions or tissue swelling (angioedema) during treatment with perindopril or other ACE inhibitors
- have heart problem
- have liver problem
- suffer from a collagen disease such as systemic lupus erythematosus or scleroderma
- are on a salt restricted diet or use salt substitutes which

contain potassium

- suffer from diabetes which is not well controlled

Perindopril tablets are not recommended for children and adolescents.

Pregnancy and breast-feeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking PERINDOSYL before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine. PERINDOSYL is not recommended during pregnancy as it may cause serious harm to your baby.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. PERINDOSYL is not recommended for mothers who are breast-feeding, your doctor may choose another treatment for you if you wish to breast-feed.

Increased risk of birth defects, fetal and neonatal morbidity and death if used during pregnancy.

-Taking other medicines

Please tell your doctor or pharmacist, if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, herbal medicines or natural products. In particular, you should check with your doctor if you are taking any of the following to be sure that it is safe to take Perindopril.

- other medicines for treating high blood pressure including diuretics (water tablets)
- potassium-sparing diuretics (e.g. spironolactone, triamterene or amiloride); potassium supplements and potassium-containing salt substitutes
- medicines for treatment of diabetes (insulin or tablets) to lower blood sugar
- lithium for treatment of mania or depression
- medicines for treatment of mental disorders such as depression, anxiety, schizophrenia or other psychoses
- allopurinol used for the treatment of

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- gout
- immunosuppressants used for the treatment of auto-immune disorders (e.g. rheumatoid arthritis) or following transplant surgery
- procainamide, a treatment for irregular heartbeat
- non-steroidal anti-inflammatory drugs (NSAIDs), medications for pain relief, including aspirin (if dose is higher or equal to 3g/day);
- vasodilators including nitrates (product that make the blood vessels become wider)
- heparin (blood thinning medication)
- co-trimoxazole (an antibiotic)
- racecadotril (a medicine for acute diarrhea)

Ask your doctor if you are not sure what these medicines are.

Tell your doctor or dentist before having an anaesthetic or surgery, because your blood pressure may fall suddenly during the anaesthesia.

HOW TO USE PERINDOSYL

- How much to use

Always take this medicine exactly as your doctor told you. Please ask your doctor or pharmacist if you are not sure.

PERINDOSYL may be used on its own or with other medicines which lower blood pressure.

Usual dose:

High blood pressure: the usual starting for treatment in adults is 4 mg once a day. After a month, this can be increased to 8 mg a day which is the maximum recommended dose.

If you are elderly, the usual starting dose is 2 mg once a day. After a month, this can be increased to 4 mg a day and if necessary to 8 mg a day depending on kidney function.

Heart failure: treatment should be started under close medical supervision with 2 mg once a day. After two weeks, it can be increased to 4 mg a day if required.

Stable coronary artery disease: the usual starting dose is 4 mg once daily. After two weeks and if 4 mg is well tolerated, this can be increased to 8

mg once daily.

Your doctor may give you a blood test to check that your kidneys are working properly before increasing the dose to 8 mg.

In case of **impaired renal or hepatic function**, your doctor will adjust the dose of PERINDOSYL for you. Treatment of these conditions is usually life-long.

It is recommended that PERINDOSYL should be taken before a meal with sufficient amount of fluid (e.g. water) in order to reduce the influence of food on the way in which the medicine works. Potassium containing food additives or salt substitutes should not be used if you use PERINDOSYL; the blood potassium concentration can be elevated too high. Also large amounts of (plain) salt (NaCl) in the diet may reduce the antihypertensive effect of PERINDOSYL.

- When to use it

Take your tablet(s) with a glass of water, preferably at the same time each day, in the morning, before a meal. If you are taking water tablets (diuretics), your doctor may decide to reduce or even discontinue these at beginning of your treatment with Perindopril.

- How long to use it

Continue taking PERINDOSYL for as long as your doctor recommends.

- If you forget to use it

It is important to take your medicine every day. However, if you forget to take one or more doses, take another as soon as you remember and then go on as prescribed. Do not take a double dose.

- If you use too much (overdose)

If you take too many tablets, contact your nearest hospital casualty department or tell your doctor immediately. The most likely effect in case of overdose is low blood pressure. If marked low blood pressure occurs (symptoms such as dizziness or faintness), lying down with the legs raised can help. Other symptoms include shock (circulatory), electrolyte disturbances, renal failure, hyperventilation

(deeper breathing), faster/ slower/ abnormal heart rate, anxiety, and cough.

- If you stop taking PERINDOSYL

Always consult your doctor, if you wish to stop taking this medicine. Even if you feel well, it may be necessary to continue taking this medicine.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

WHILE YOU ARE USING PERINDOSYL

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking PERINDOSYL.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give PERINDOSYL to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

However, PERINDOSYL does not affect alertness but different reactions such as dizziness or weakness in relation to the decrease in blood pressure may occur in certain patients, especially in the beginning of treatment or when increasing the dose. If affected, your ability to drive or to operate machinery may be impaired.

SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common side effects:

- dizziness, headache, vertigo, sensation of pins and needles

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- visual disturbances (e.g. blurred vision, eye pain)
- tinnitus (ringing in the ears)
- light-headedness due to low blood pressure
- cough, shortness of breath
- abdominal pain, constipation, diarrhoea, changes in your sense of taste, feeling of indigestion, nausea, vomiting
- skin rashes, itching
- muscle cramps
- lack of energy

Uncommon side effects:

- low blood sugar level, high blood potassium level, low blood sodium level
- changes in mood or sleep
- dizziness, fainting
- unusually fast or irregular heart beat
- bronchospasm (tightening of the chest, wheezing and shortness of breath)
- dry mouth
- skin rash
- swelling of face, lips, mouth, tongue or throat
- sweating
- sensitive to lights
- muscle pains
- kidney problems
- impotence
- chest pain, tiredness, peripheral edema, fever
- increased blood urea and creatinine
- fall

Rare side effects:

- psoriasis aggravation

Very rare side effects:

- changes in the blood cell count: Your doctor may decide to carry out blood tests at intervals to monitor for this
- confusion
- angina pectoris (chest tightness)
- irregular heartbeat, heart attack and stroke
- eosinophilic pneumonia (a rare type of pneumonia), rhinitis (blocked up or runny nose)
- pancreatitis (inflammation of the pancreas)
- hepatitis (inflammation of the liver)
- erythema multiforme (skin

reaction disorder resulting from allergic reaction provoked by many different causes)

- acute renal failure

However, if you have difficulty in breathing, contact your doctor immediately:

These are symptoms of a serious reaction (angioedema) which can occur with all other drugs of this type (ACE inhibitors). It must be treated immediately, usually in hospital.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

STORAGE AND DISPOSAL OF PERINDOSYL

: Storage

Keep out of the reach and sight of children.

Store below 30°C.

Store in the original package in order to protect from moisture.

Do not use Perindosyl after the expiry date which is stated on the blister and carton.

: Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

PRODUCT DESCRIPTION

: What it looks like

Tablets are white, round, biconvex tablet scored on one side and debossed with 4 on the reverse side. The tablet can be divided into equal halves.

: Ingredients

Active ingredient

Each tablet contains 4mg perindopril tert-butylamine, equivalent to 3.338 mg perindopril.

Inactive ingredients

Microcrystalline cellulose
Silicified microcrystalline cellulose
Polacrillin potassium
Silicone dioxide
Colloidal anhydrous silica
Magnesium stearate
Hydroxypropylbetadex

MAL Number

MAL11010008AZ

MANUFACTURER

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PRODUCT REGISTRATION HOLDER

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