

PERINDOSYL TABLETS

Consumer Medication Information Leaflet (RiMUP)

Perindopril tert-butylamine 2mg, 4mg & 8mg

WHAT IS IN THIS LEAFLET:

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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 is condition called angioedema);

- if you have hereditary tendency to tissue swelling of unknown origin (hereditary or idiopathic angioedema),
- if you are more than 3 months pregnant. (it is also better to avoid Perindosyl in early pregnancy)

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 case, among others, if you suffer from heart failure, impaired kidney function or disorders in the salt and fluid balance, e.g. because you take diuretics (medicines that increase urine production) or keep 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 hypersensitivity reactions or tissue swelling (angioedema) during treatment with perindopril or other ACE inhibitors. Angioedema more frequently occur in patients with black skin colour than in patients with non-black skin colour
- have heart problem
- liver problem
- a kidney problem

- receiving dialysis
- 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
- are breast-feeding

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 first trimester of pregnancy. It is also contraindicated during the 2nd and 3rd trimester of 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.

-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 (eg spironolactone, triamterene or amiloride); potassium supplements

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and potassium-containing salt substitutes

- medicines for the treatment of diabetes (insulin or tablets) to lower blood sugar
- lithium for treatment of mania or depression
- medicines for the treatment of mental disorders such as depression, anxiety, schizophrenia or other psychoses;
- allopurinol used for the treatment of gout
- immunosuppressants used for the treatment of auto-immune disorders (eg 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);
- medicines used for the treatment of low blood pressure, shock or asthma (eg ephedrine, noradrenaline or adrenaline)
- vasodilators including nitrates (product that make the blood vessels become wider)
- heparin (blood thinning medication)

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

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 kidney or liver function,** your doctor will adjust the dose of PERINDOSYL for you.

Treatment of these conditions is usually life-long.

If you are taking water tablets (diuretics), your doctor may decide to reduce or even discontinue these at beginning of your treatment with Perindopril.

- 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.

- 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, kidney 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.

Taking Perindopril with food and drink tablets.

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

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amounts of (plain) salt (NaCl) in the diet may reduce the antihypertensive effect of PERINDOSYL

- *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.

Other possible side effects

Common (affecting less than 1 in every 10 people):

- cough, shortness of breath
- light-headedness due to low blood pressure
- headache, dizziness, vertigo, tiredness, pins and needles, visual disturbances (eg blurred vision, eye pain), tinnitus (sensation of noises in the ears)
- nausea, vomiting, abdominal pain, changes in your sense of taste, feeling of indigestion, diarrhoea, constipation
- skin rashes, itching

Uncommon (affecting less than 1 in every 100 people):

- changes in mood or sleep
- bronchospasm (tightening of the chest, wheezing and shortness of breath)
- dry mouth
- muscle cramp
- kidney problems
- impotence
- sweating

However, if you notice any of the following side effects, contact your doctor immediately:

- swelling of the face, lips, mouth, tongue or throat
- difficulty in breathing
- dizziness or fainting
- unusually fast or irregular heart beat

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.

Very rare (affecting less than 1 in every 10.000 people):

- irregular heartbeat, heart attack and stroke (these have been reported with ACE inhibitors in association with low blood pressure)
- angina pectoris (chest tightness)
- 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)
- changes in the blood cell count: your doctor may decide to carry out blood tests at intervals to monitor for this.

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 calling Tel: **03-78835550**, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

STORAGE AND DISPOSAL OF PERINDOSYL

-Storage

Keep out of the reach and sight of children.

Do not store above 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. The expiry date refers to the last day of that month.

- 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

PERINDOSYL 2mg tablets

Tablets are white, round, biconvex tablet debossed with 2 on one side.

PERINDOSYL 4mg tablets

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.

PERINDOSYL 8mg tablets

Tablets are white, round, biconvex tablet debossed with 8 on one side.

-Ingredients

- Active ingredient

PERINDOSYL 2mg tablets

Each tablet contains 2mg perindopril tert-butylamine, equivalent to 1.669 mg of perindopril.

PERINDOSYL 4mg tablets

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

PERINDOSYL 8mg tablets

Each tablet contains 8mg perindopril tert-butylamine, equivalent to 6.676 mg of perindopril.

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- *Inactive ingredients*

microcrystalline cellulose,
silicified microcrystalline
cellulose, polacrillin potassium,
silicon dioxide, colloidal
anhydrous silica, magnesium
stearate and
Hydroxypropylbetadex.

MAL numbers:

Perindosyl 2mg- MAL11010007A

Perindosyl 4mg- MAL11010008A

Perindosyl 8mg- MAL11030102A

MANUFACTURER

Lek Pharmaceuticals d.d

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**PRODUCT REGISTRATION
HOLDER**

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30/12/2014

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