

PERINACE TABLET

Perindopril erbumine (4mg, 8mg)

What is in this leaflet

1. What PERINACE TABLET is used for
2. How PERINACE TABLET works
3. Before you take PERINACE TABLET
4. How to take PERINACE TABLET
5. While you are taking PERINACE TABLET
6. Side effects
7. Storage and Disposal of PERINACE TABLET
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What PERINACE TABLET is used for

Perinace is an angiotensin converting enzyme (ACE) inhibitor.

Perinace is used:

- to treat arterial hypertension,
- to treat heart failure (when 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 PERINACE TABLET 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 take PERINACE TABLET

When you must not take it

- **Do not take PERINACE**
- if you are allergic (hypersensitive) to perindopril or any of the other

ingredients of this medicine, or to any other ACE inhibitor.

- if you have experienced symptoms such as wheezing, swelling of the face, tongue or throat, intense itching or severe skin rashes with previous ACE inhibitor treatment or if you or a member of your family have had these symptoms in any other circumstances (a condition called angioedema).
 - if you are more than 3 months pregnant (It is also better to avoid Perinace in early pregnancy – see pregnancy section).
 - if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
 - if you are having dialysis or any other type of blood filtration. Depending on the machine that is used, Perinace may not be suitable for you,
 - if you have kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis).
 - if you are being treated with sacubitril/valsartan, a medicine for heart failure (see “Warning and Precaution” and “Other medicines and Perinace”).
- Before you start to use it
- Check with your doctor, pharmacist or dentist before taking PERINACE TABLET if:
- have aortic stenosis (narrowing of the main blood vessel leading from the heart) or hypertrophic cardiomyopathy (heart muscle disease) or renal artery stenosis (narrowing of the artery supplying the kidney with blood),
 - have any other heart problems,
 - have liver problems,
 - have kidney problems or if you are receiving dialysis,
 - have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism),

- suffer from a collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma,
- have diabetes,
- are on a salt restricted diet or use salt substitutes which contain potassium,
- are to undergo anaesthesia and/or major surgery,
- are to undergo LDL apheresis (which is removal of cholesterol from your blood by a machine),
- are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings,
- have recently suffered from diarrhoea or vomiting, or are dehydrated,
- have been told by your doctor that you have an intolerance to some sugars,
- are taking any of the following medicines used to treat high blood pressure:
 - an “angiotensin II receptor blocker” (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems.
 - aliskiren.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals. See also information under the heading “Do not take Perinace”.

- are of black origin since you may have a higher risk of angioedema and this medicine may be less effective in lowering your blood pressure than in non-black patients.
- are taking any of the following medicines, the risk of angioedema is increased:
 - racecadotril (used to treat diarrhoea)

PERINACE TABLET

Perindopril erbumine (4mg, 8mg)

- sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTOR inhibitors (used to avoid rejection of transplanted organs),
- sacubitril/valsartan, used to treat long-term heart failure (see “Do not take Perinace”).

Angioedema

Angioedema (a severe allergic reaction with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing) has been reported in patients treated with ACE inhibitors, including Perinace. This may occur at any time during treatment. If you develop such symptoms, you should stop taking Perinace and see a doctor immediately.

Use in children and adolescents

The use of perindopril in children and adolescents up to the age of 18 years is not recommended.

Pregnancy and breast-feeding

You must tell your doctor if you think you are (or might become) pregnant. Perinace is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

Driving and using machines

Perinace usually does not affect alertness but dizziness or weakness due to low blood pressure may occur in certain patients. If you are affected in this way, your ability to drive or to operate machinery may be impaired.

PERINACE contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken or might take any other medicines. Treatment with Perinace can be affected by other medicines. Your doctor may need to change your dose and/or to take other precautions. These include:

- other medicines for high blood pressure, including angiotensin II receptor blocker (ARB), aliskiren (see also information under the headings “Do not take Perinace” and “Warning and precautions”), or diuretics (medicines which increase the amount of urine produced by the kidneys),
- potassium-sparing drugs (e.g., triamterene, amiloride), potassium supplements or potassium containing salt substitutes, other drugs which can increase potassium in your body (such as heparins and co-trimoxazole also known as trimethoprim/sulfamethoxazole),
- potassium-sparing drugs used in the treatment of heart failure: eplerenone and spironolactone at doses between 12.5 mg to 50 mg by day,
- lithium for mania or depression,
- non-steroidal anti-inflammatory drugs (e.g., ibuprofen) for pain relief or high dose aspirin,
- medicines to treat diabetes (such as insulin, metformin, gliptines),
- baclofen (used to treat muscle stiffness in diseases such as multiple sclerosis),
- medicines to treat mental disorders such as depression, anxiety, schizophrenia etc (e.g., tricyclic antidepressants, antipsychotics),
- anaesthetics
- immunosuppressants (medicines which reduce the defence mechanism of the body) used for the treatment of auto-immune disorders or following transplant surgery (e.g., ciclosporin, tacrolimus),

- trimethoprim (for the treatment of infections),
- estramustine (used in cancer therapy),
- medicines, which are most often used to treat diarrhea (racecadotril)
- medicines used to avoid rejection of transplanted organs (sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTOR inhibitors). See section “Warnings and precautions”
- sacubitril/valsartan (used to treat long-term heart failure). See sections “Do not take Perinace” and “Warnings and precautions”.
- allopurinol (for the treatment of gout),
- procainamide (for the treatment of an irregular heart beat),
- vasodilators including nitrates (products that make the blood vessels become wider),
- medicines used for the treatment of low blood pressure, shock or asthma (e.g., ephedrine, noradrenaline or adrenaline),
- gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis).

How to take PERINACE TABLET

Taking PERINACE with food and drink

It is preferable to take Perinace before a meal.

- How much to take

The recommended dosages are as follows:

High blood pressure: the usual starting and maintenance doses are 4 mg once daily. After one month, the dose can be increased to 8 mg daily if required. The maximum daily dose is 8 mg per day for the treatment high blood pressure.

PERINACE TABLET

Perindopril erbumine (4mg, 8mg)

If you are over 65 years of age, the starting dose is usually 2 mg daily. After a month, the dose can be increased to 4 mg per day and, if necessary, to 8 mg per day.

Heart failure: the usual starting dose is 2 mg once daily. After two weeks, the dose can be increased to 4 mg, which is the maximum recommended dose for treating heart failure.

Stable coronary artery disease: the usual starting dose is 4 mg once daily. After two weeks, the dose can be increased to 8 mg once daily, which is the maximum recommended dose for this indication.

-When to take it

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Swallow your tablet with a glass of water, preferably at the same time each day, in the morning, before a meal.

Your doctor will decide on the correct dose for you.

If you are over 65 years of age, the usual starting dose is 2 mg once daily. After a week, the dose can be increased to 4 mg once a day and, after a second week of treatment, to 8 mg once daily.

- How long to take it

As the treatment for high blood pressure is usually life-long, you should discuss with your doctor before stopping this medicinal product. If you have any further questions on the use of this product, ask your doctor or pharmacist.

-If you forget to take it

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of Perinace, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

If you take too many tablets, contact your nearest accident and emergency department or tell your doctor immediately. The most likely effect in case of overdose is low blood pressure which can make you feel dizzy or faint. If this happens, lying down with the legs raised can help.

- If you stop taking:

As the treatment with Perinace is usually life-long, you should discuss with your doctor before stopping this medicinal product.

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

While you are taking PERINACE TABLET

- Things you must do

Do not stop taking PERINACE TABLET without talking to your doctor. Take this medicine on a regular basis for as long as your doctor keeps prescribing it.

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Perinace before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Perinace. Perinace is not recommended in early pregnancy and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breastfeeding or about to start breast-feeding. Perinace is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breastfeed, especially if your baby is newborn, or was born prematurely.

- 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 PERINACE TABLET to anyone else, even if they have the same symptoms or condition as you.

Side effects

Like all medicines, PERINACE TABLET can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

See a doctor straight away if you notice any of the following – you may need urgent medical treatment:

PERINACE TABLET

Perindopril erbumine (4mg, 8mg)

- swelling of the face, lips, mouth, tongue or throat, difficulty in breathing (angioedema) (See “Warning and precaution”) (Uncommon),
- severe dizziness or fainting due to low blood pressure (Common),
- unusual fast or irregular heartbeat, chest pain (angina) or heart attack (Very rare),
- weakness of arms or legs, or problems speaking which could be a sign of a possible stroke (Very rare),
- sudden wheeziness, chest pain, shortness of breath, or difficulty in breathing (bronchospasm) (Uncommon),
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell (Very rare),
- yellowing of the skin or eyes (jaundice) which could be a sign of hepatitis (Very rare),
- skin rash which often starts with red itchy patches on your face, arms or legs (erythema multiforme) (Very rare).

Other possible side effects:

- **Common:** headache, dizziness, vertigo, pins and needles, vision disturbances, tinnitus (sensation of noises in the ears), cough, shortness of breath (dyspnoea), gastrointestinal disorders (nausea, vomiting, abdominal pain, taste disturbances, dyspepsia or difficulty of digestion, diarrhoea, constipation), allergic reactions (such as skin rashes, itching), muscle cramps, feeling of weakness.
- **Uncommon:** mood swings, sleep disturbances, dry mouth, intense itching or severe skin rashes, formation of blister clusters over the skin, kidney problems, impotence, sweating, excess of eosinophils (a type of white blood cells), somnolence, fainting, palpitations,

tachycardia, vasculitis (inflammation of blood vessels), photosensitivity reaction (increased sensitivity of the skin to sun), arthralgia (joint pain), myalgia (muscle pain), chest pain, malaise, oedema peripheral, fever, fall, change in laboratory parameters: high blood level of potassium reversible on discontinuation, low level of sodium, hypoglycaemia (very low blood sugar level) in case of diabetic patients, increased blood urea, and increased blood creatinine.

- **Rare:** psoriasis worsening, changes in laboratory parameters: Increased level of liver enzymes, high level of serum bilirubin.

- **Very rare:** confusion, eosinophilic pneumonia (a rare type of pneumonia), rhinitis (blocked up or runny nose), acute renal failure, changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets.

Concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits which may be due to inappropriate ADH (anti-diuretic hormone) secretion can occur with ACE inhibitors. If you have these symptoms contact your doctor as soon as possible

- **Frequency not known (cannot be estimated from available data)** - discoloration, numbness and pain in fingers or toes (Raynaud’s phenomenon)

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 PERINACE TABLET

- Storage

Store below 30°C. Store in original container.

Keep out of reach of children.

- 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.

Shelf life:

- Shelf life: please refer to outerbox
- Note: To be consumed within 6 months after opening the aluminium pouch

Product Description

- What it looks like

Perinace Tablet 4mg

An oblong shape, scored, white to off-white tablet

Perinace Tablet 8mg

A white oval biconvex shape tablet, plain on one side and score line on the other side.

The tablet can be divided into equal halves.

Ingredients

- Active ingredient(s)

Perinace 4mg and 8mg contain Perindopril erbumine 4mg and 8mg respectively.

Inactive ingredients

- Microcrystalline cellulose
- Magnesium stearate
- Fumed silicone dioxide
- Lactose monohydrate

PERINACE TABLET

Perindopril erbumine (4mg, 8mg)

- MAL number:

Perinace Tablet 4mg

MAL04103441AZ

Perinace Tablet 8mg

MAL12085073AZ

Manufacturer

Duopharma Manufacturing (Bangi)

Sdn.Bhd.

Lot No 2 & 4, Jalan P/7, Section 13,

Bangi Industrial Estate,

43650 Bandar Baru Bangi,

Selangor Darul Ehsan, Malaysia.

Product Registration Holder

Duopharma Manufacturing (Bangi)

Sdn.Bhd.

Lot No 2, 4, 6, 8 & 10, Jalan P/7,

Section 13, Bangi Industrial Estate,

43650 Bandar Baru Bangi,

Selangor Darul Ehsan, Malaysia

Date of revision

08/10/2021

Serial Number

NPRA(R2/2)210929/761