# **PERINACE**

Perindopril erbumine (4mg, 8mg)

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#### What Perinace is used for

Perinace is used in treating hypertension and symptomatic heart failure.

#### **How Perinace works**

Perinace is an angiotensin converting enzyme (ACE) inhibitor. It works by widening the blood vessels, which makes it easier for the heart to pump blood through them.

### Before you use Perinace

- When you must not take it
- if you are allergic (hypersensitive) to perindopril, to any other ACE inhibitor or to any of the other ingredients of Perinace,
- if you are more than 3 months pregnant. (It is also better to avoid Perinace, tablet in early pregnancy see pregnancy and breastfeeding section.)
- 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).

## - Before you start to take it

Please inform your doctor if:

• if you 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).
- if you have any other heart problems,
- if you have liver problems,
- if you have kidney problems or if you are receiving dialysis,
- if you suffer from a collagen vascular disease such as Systemic lupus erythematosus (is an autoimmune disease in which the body's immune system mistakenly attacks healthy tissue. It can affect the skin, joints, kidneys, brain and other organs).
- if you are diabetic,
- if you are on a salt restricted diet or use salt substitutes which contain potassium,
- if you are going to have a general anaesthetic and/or major surgery,
- if you are to undergo LDL apheresis (which is removal of cholesterol from your blood by a machine),
- if you are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings,
- if you have recently suffered from diarrhoea or vomiting, or are dehydrated,
- if you have been told by your doctor that you have an intolerance to some sugars.
- Perinace is not recommended for use in children and adolescents

# - <u>Taking other medicines</u>

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Treatment with Perinace can be affected by other medicines:

- other medicines for high blood pressure, including diuretics (medicines which increase the amount of urine produced by the kidneys),
- potassium-sparing diuretics (spironolactone, triamterene, amiloride), potassium supplements or potassium-containing salt substitutes,
- 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 or metformin),
- medicines to treat mental disorders such as depression, anxiety, schizophrenia etc (e.g. tricyclic antidepressants, antipsychotics),
- 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).

#### **How to use Perinace**

Always comply with your doctor's prescription. You should check with your doctor or pharmacist if you are not sure.

#### - How much to take

The usual dosages are as follows:

Hypertension: the usual starting and maintenance dose is 4 mg once daily. After one month, this can be increased to 8 mg once a day if required. 8 mg a day is the maximum recommended dose for arterial hypertension.

If you are 65 or older, the usual starting dose is 2 mg once a day. After a month this can be increased to 4 mg once a day and then if necessary to 8 mg once daily.

Symptomatic heart failure: the usual starting dose is 2 mg once daily.

After two weeks, this can be increased to 4 mg once daily.

#### - When to use it

It is recommended to take Perinace tablets in the morning before meal to reduce the influence of food on the way in which the medicine works. It is best to take your tablet(s) with a glass of water at the same time each day.

#### - How long to use it

Continue taking your medicine for as long as your doctor tells you.

Medicines for high blood pressure or heart failure will normally have to be taken for the rest of your life. If you stop taking Perinace tablets your condition may get worse.

#### - If you forget to take it

It is important to take your medicine every day as a regular treatment is more effective. However if you forget to take Perinace, simply take your treatment the next day as usual. Do not take a double dose to make up for a forgotten dose.

## - <u>If you take too much (overdose</u>)

If you have taken too many tablets, contact your doctor or the nearest hospital immediately. The most likely event in case of overdose is hypotension. If marked hypotension occurs (associated with dizziness or vertigo), it can be treated by lying the patient down with their legs raised.

## While you are using it

# - Things you must do

Pregnancy and Breasfeeding

You must tell your doctor if you think that you are (or might become) pregnant. Your doctor will normally advise you to stop taking Perinace, tablet 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.

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

Ask your doctor or pharmacist for advice before taking any medicine.

## - Things you must not do

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Do not take Perinace 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.

# - Things to be careful of

Driving and using machines

You may feel dizzy or tired when taking Perinace, just as with other ACE Inhibitors. If this happens, do not drive or use machines. You must talk to your doctor about this.

#### Side effects

Like all medicines, Perinace tablet can cause side effects, although not everyone gets them.

Common (affecting 1 or more than 1 in 100 but less than 1 in 10 patients)

- cough, shortness of breath
- feeling faint due to low blood pressure (especially when you start Perinace, or when the amount is increased, or when you also take diuretic (water tablets)
- headache, feeling dizzy or tired, feeling dizzy with a spinning sensation (vertigo), pins and needles, muscle cramps, blurred vision, eye pain, sensation of noises in the ears (tinnitus)
- feeling or being sick, stomach pain or indigestion,

• changes in your sense of taste, diarrhea, constipation, skin rash, itching.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

# **Storage and Disposal of Perinace**

#### - Storage

Keep your medicine in its original packaging until it is time to take them. Keep out the reach and sight of children. Do not store above 30°C.

#### - Disposal

If your doctor tells you to stop taking Perinace or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

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
- Perinace Tablet 4mg: Scored 1 side, white to off-white oblong.
- Perinace Tablet 8mg: Oval white color tablet biconvex, scored in one side.

Each strength of tablet is available in a packaging containing 30 tablets blister.

## - Ingredients

Active ingredient:

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

#### Inactive ingredients:

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

#### - MAL number

- Perinace Tablet 4mg: MAL04103441A
- Perinace Tablet 8mg: MAL12085073A

#### Manufacturer

UPHA PHARMACEUTICAL MFG (M) SDN BHD (53667-M) Lot 2&4, Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor Darul Ehsan

# **Product Registration Holder**

CCM PHARMACEUTICALS SDN BHD (277454-W) Lot 2&4, Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor Darul Ehsan

#### **Date of Revision**

18/04/2014