

## Package Leaflet: Information for the user

### Perindopril 2mg Tablets

### Perindopril 4mg Tablets

### Perindopril 8mg Tablets

Perindopril tert-butylamine

#### **Read all of this leaflet carefully before you start taking this medicine because it contains important information for you**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet:

1. What Perindopril is and what it is used for
2. What you need to know before you take Perindopril Tablets
3. How to take Perindopril Tablets
4. Possible side effects.
5. How to store Perindopril Tablets
6. Contents of the pack and other information

#### **1. What Perindopril is and what it is used for**

PERINDOPRIL belongs to a group of medicines called ACE inhibitors. These work by widening the blood vessels. This makes it easier for your heart to pump blood through the body.

Perindopril 2 mg or 4 mg tablets are used to:

- treat high blood pressure (hypertension)
- treat heart failure (a condition where the heart is unable to pump enough blood to meet the body's needs)
- 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.

Perindopril 8 mg tablets are used to:

- treat high blood pressure (hypertension)
- 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.

## 2. What you need to know before you take Perindopril Tablets

### Do not take Perindopril

- If you are allergic (hypersensitive) to perindopril or to any of the other ingredients of Perindopril Tablets or to any other ACE inhibitor (see section 6),
- if you have in the past suffered from acute swelling of the face, tongue or larynx (angioneurotic syndrome), regardless of whether or not it has been caused by treatment with a similar medicine (ACE inhibitor).
- If you are more than 3 months pregnant. (It is also better to avoid Perindopril in early pregnancy – see pregnancy section.)
- If you are already taking a medicine containing aliskiren and you suffer from diabetes or your kidney's do not work properly

Children and adolescents

Perindopril is not recommended for use in children and adolescents.

### Warnings and precautions

#### Talk to your doctor before taking Perindopril if:

- you are already taking aliskiren and a medicine called an ARB (angiotensin II receptor blocker) as your doctor may want to change the medicines you are taking
- you have narrowing of the heart valves (aortic or mitral stenosis) or heart muscle disease (hypertrophic cardiomyopathy) or narrowing of the artery supplying the kidney with blood (renal artery stenosis)
- if you have recently had a kidney transplant
- you have any other heart or liver or kidney problems, or if you are having dialysis
- you have diabetes which is not well controlled
- you have been told to limit the salt in your diet or to use a salt-substitute containing potassium
- you have a collagen disease such as systemic lupus erythematosus or scleroderma.
- you are going to have or are having treatment to reduce the effects of an allergy to bee or wasp stings
- you are going to have cholesterol removed from your blood by a machine (LDL apheresis).
- You must tell your doctor if you think you are (or might become) pregnant. Perindopril 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).

In the event of the occurrence of a feeling of tightness in the chest and swelling of the face and tongue (angioneurotic oedema), you should immediately notify your doctor and stop the treatment with Perindopril 2 mg, 4 mg or 8 mg Tablets. This applies to all ACE inhibitors.

Tell the doctor or pharmacist that you are taking Perindopril if:

- you are about to have an operation or a general anaesthetic
- you have recently had diarrhoea or vomited
- your blood pressure is not sufficiently lowered due to ethnic affiliation (particularly in patients with black skin colour)

#### Other medicines and Perindopril

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

In particular, talk to your doctor before taking Perindopril if you are taking:

- medicines for high blood pressure (e.g. aliskiren) including water tablets (diuretics)
- water tablets (diuretics) which affect potassium, such as spironolactone, triamterene or amiloride
- medicines to increase your level of potassium
- heparin (for thinning the blood) can also affect potassium levels in your blood
- medicines for diabetes (insulin or tablets)

- lithium (for mania or depression)
- medicines for mental illness such as depression, anxiety, schizophrenia or other psychosis
- allopurinol for gout
- medicines to treat auto-immune disorders (such as rheumatoid arthritis) or given after transplant surgery. These are called immunosuppressants.
- procainamide (for irregular heartbeat)
- non-steroidal anti-inflammatory drugs (NSAIDs such as ibuprofen, diclofenac), including aspirin for pain
- medicines for low blood pressure, shock or asthma (including ephedrine, noradrenaline or adrenaline)
- medicines that make the blood vessels wider (vasodilators, such as nitrates).
- therapy with injectable gold (sodium aurothiomalate)

Ask your doctor if you are not sure what these medicines are. Tell the doctor if you have taken any of the medicines listed above in the past, but have now stopped.

### **Perindopril with food and drink**

It is recommended to take Perindopril tablets in the morning before a meal 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 Perindopril.

### **Pregnancy and Breastfeeding:**

#### **Ask your doctor or pharmacist for advice before taking any 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 Perindopril before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Perindopril. Perindopril 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.

#### **Breastfeeding:**

Tell your doctor if you are breast-feeding or about to start breast-feeding. Perindopril 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.

#### **Driving and using machines:**

Perindopril Tablets 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 operate machinery may be impaired.

#### **Perindopril tablets contain lactose**

The tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine

### **3. How to take Perindopril Tablets**

Your doctor will decide on the amount of perindopril you should start to take. This may be increased depending on your condition and other medicines you are taking. Always take Perindopril exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Do not change the amount of medicine you take unless your doctor tells you. Perindopril may be used on its own, or with other medicines which lower blood pressure.

- Take Perindopril tablets by mouth only.
- Take them in the morning, before a meal.

- It is best to take your tablet(s) with a glass of water at the same time each day.

Perindopril is not recommended for use in children and adolescents.

The usual dose is:

**High blood pressure:**

- Starting dose - 4 mg Perindopril tert-butylamine each day
- after a month, this may be raised to 8 mg each day.

8 mg each day is the highest amount normally used.

In older people with high blood pressure the daily amounts are usually:

- 2 mg each day
- after a month, this may be raised to 4 mg each day.

8 mg each day is the highest amount used.

Perindopril 2 mg, 4 mg or 8 mg Tablets should only be used with other medicines for high blood pressure which are not also ACE inhibitors.

If you are **taking water tablets** (diuretics):

- your doctor may stop them 2 to 3 days before you start taking Perindopril .This is to prevent a fall in your blood pressure.
- if needed, you can start taking water tablets again after you have started Perindopril .
- if it is not possible to stop your water tablets, then you can take 2 mg of perindopril tert-butylamine as well.

Your doctor or pharmacist will tell you exactly what you should do.

The doctor may start you with 2 mg perindopril tert-butylamine if:

- your blood pressure is very high
- you do not have enough water in your body (dehydrated).
- you have a low level of salt in your blood.
- you have a heart problem which means that it has difficulty in pumping blood through the body (cardiac decompensation).
- you have high blood pressure due to the blood vessels in the kidneys being blocked (constriction of the arteries).
- If you have an excessive drop in blood pressure following the initial dose.

**Heart failure:**

The 8 mg strength is not suitable for treatment of this condition.

- Starting dose 2 mg Perindopril tert-butylamine each day.
- after 2 weeks, this may be raised to 4 mg each day.

**Stable coronary artery disease:**

- the usual starting dose is 4 mg Perindopril tert-butylamine once daily
- after two weeks, this may be raised to 8 mg each day.

In older people with stable coronary artery disease the daily amounts are usually:

- 2 mg each day
- after one week, this may be raised to 4 mg each day
- and after a further week to 8 mg each day which is the highest amount used.

**If you take more perindopril than you should**

Immediately contact your doctor or your nearest accident and emergency department if you have taken too high a dose.

The following effects may happen: low blood pressure, shock, kidney problems, fast breathing, fast heartbeat, uneven heartbeat (palpitations), slow heartbeat, feeling dizzy or anxious and cough.

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 forget to take perindopril**

Do not take a double dose to make up for a forgotten dose.  
If you have forgotten to take one or more tablets, you should skip the tablets which you have forgotten. Contact your doctor if in doubt.

### **If you stop taking perindopril**

Do not stop taking Perindopril without talking to your doctor.  
Medicines for high blood pressure or heart failure will normally have to be taken for the rest of your life. If you stop taking Perindopril your condition may get worse.

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

## **4. Possible Side Effects**

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

If any of the following effects happen, **stop taking your tablets and tell your doctor immediately:**

- swelling of the face, lips, mouth, tongue or throat
- difficulty in breathing
- feeling dizzy or faint
- very fast or uneven heartbeat.

This is a very rare but serious reaction called angioedema, which can happen with all medicines of this type (ACE inhibitors). You must get treatment immediately, usually in hospital.

**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 Perindopril, or when the amount is increased, or when you also take 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, diarrhoea, constipation, skin rash, itching.

**Uncommon** (affecting 1 or more than 1 in 1000 but less than 1 in 100 patients)

- changes in mood or sleep
- tight feeling in the chest, wheezing and short of breath (bronchospasm)
- dry mouth
- kidney problems
- unable to get an erection
- sweating
- wheezing, swelling of the face, tongue or throat, intense itching, skin rash, fainting or feeling dizzy (angioedema).

**Very rare** (affecting less than 1 in 10,000 patients)

- feeling confused
- uneven heartbeat, chest pain that happens in heart disease (angina), heart attack and stroke (these have happened with ACE inhibitors in people with low blood pressure)
- chest infection (eosinophilic pneumonia), blocked up or runny nose (rhinitis)
- inflamed pancreas (pancreatitis)
- inflamed liver (hepatitis)
- skin reaction like an allergy (erythema multiforme)
- changes in the blood. Your doctor may carry out blood tests to check for this.
- Acute kidney problems

**Not known frequency**

- In case of diabetic patients, hypoglycaemia (very low blood sugar level) can occur
- Vasculitis (inflammation of blood vessels) have been reported

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V\\*](#). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Perindopril Tablets**

- Keep this medicine out of the sight and reach of children.
- Do not store above 30°C.

Do not use this medicine after the expiry date which appears on the packet after “do not use after” or “exp”. The first 2 figures show the month, while the last figures show the year. The expiry date refers to the last day of that month.

Do use this medicine if you notice any discolouration of the tablets.

Medicines should not be disposed of via wastewater or in the household refuse. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

**6. Contents of the pack and other information****What Perindopril Tablets contains**

The active substance is:

Perindopril tert-butylamine.

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

Each Perindopril 4 mg tablet contains 4 mg of perindopril tert-butylamine salt equivalent to 3.338mg of perindopril.

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

Other ingredients (excipients) are:

Hydrophobic colloidal silica, microcrystalline cellulose, lactose and magnesium stearate.

**What Perindopril Tablets looks like and contents of the pack**

2 mg:

White, round, biconvex tablets, plain on both sides. Tablet dimension: 5.00 mm

4 mg:

White, oblong tablets with a score line on both sides, 'PP' on one side and '4' on the other. The tablets can be divided into equal halves. Tablet dimensions: 8.00 mm x 4.00 mm

8 mg:

White, round, biconvex tablets with 'PP' on one side and '8' on the other. Tablet dimension: 8.00 mm

Each strength of tablet is available in packaging containing 30 in alu-alu blister packaging.

### **Marketing Authorisation Holder and Manufacturer**

#### Marketing Authorisation holder

Glenmark Pharmaceuticals Europe Ltd,  
Laxmi House, 2-B Draycott Avenue,  
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#### Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

Netherlands:	Perindopril tert-butylamine Glenmark 2mg, 4mg, 8mg Tabletten
Finland:	Perindopril Glenmark
France:	Perindopril Zydus 2mg, 8mg comprimé Perindopril Zydus 4mg comprimé sécable
Germany:	Perindopril Erbumin Glenmark 4mg Tabletten
Ireland:	PRINDEX 2mg, 4mg, 8mg
Italy:	Perindopril EG 2mg, 4mg and 8mg compresse
Spain:	Perindopril Glenmark 2mg, 4mg, 8mg comprimidos EFG
United Kingdom:	Perindopril 2mg, 4mg, 8mg Tablets

This leaflet was last revised in: February 2014