Read all of this leaflet carefully before you start taking this medicine

• Keep this leaflet. You may need to read it again.
• If you have any further questions, consult your doctor or pharmacist.
• This medicine has been prescribed for you. Do not pass it on to others.

If you may harm them, even if the symptoms are the same as yours.
• If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What are Perindopril tablets and what they are used for?
2. What you should know before you take Perindopril tablets.
3. How are Perindopril tablets taken?
4. Possible side effects.
5. How to store Perindopril tablets.
6. Further information.

1. What are Perindopril tablets and what they are 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 2mg or 4mg tablets are used to:
• treat high blood pressure (hypertension)
• help to control the blood pressure of your body
• also reduce the risk of cardiac events, such as heart attack, in patients with stable coronary artery disease as a condition when 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 8mg 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 as a condition when 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. Before you take Perindopril tablets

Do not take Perindopril tablets:
• If you are allergic (hypersensitive) to perindopril or to any of the other ingredients of Perindopril tablets or to any other ACE inhibitors (see Further information, section 6).
• If you have in the past suffered from acute swelling of the face, tongue or throat (angioneurotic syndrome), regardless of whether or not it has been caused by bee or wasp stings
• If you have in the past suffered from acute swelling of the face, tongue or larynx (hypersensitive) to perindopril or to any of the other ingredients of Perindopril tablets. The tablets contain lactose. If you have been told by your doctor that you have an allergy to some sugars, contact your doctor before taking this medicine.
• If you have recently been told by your doctor or pharmacist that you have diabetes (meat and kidney disease). (renal artery stenosis)
• White blood cells (leukocytes) which affect potassium, such as spironolactone, triamterene or amiloride
• The tablets contain lactose. If you have been told by your doctor that you have an allergy to some sugars, contact your doctor before taking this medicine.
• If you have recently had diarrhoea or vomited
• Take special care with Perindopril tablets

Talk to your doctor before taking Perindopril tablets if:
• you have narrowing of the heart valves (bicuspid or aortic stenosis) or heart muscle disease (hypertrophic cardiomyopathy)
• you have diabetes
• you have had a kidney transplant
• you have any other heart or kidney problems, or you are having dialysis
• you have a collagen disease such as systemic lupus erythematosus or scleroderma
• you are going to have an operation to improve the effects of an allergy to bee or wasp stings
• you are going to have chemotherapy removed from your blood by a machine (LDL apheresis). You must tell your doctor if you have (or might become) pregnant.

Perindopril tablets are 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 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 tablets 2mg, 4mg or 8mg. This applies to all ACE inhibitors.

Tell the doctor or pharmacist that you are taking Perindopril tert-butyramine if:
• you are about to have an operation or a general anaesthetic
• you have recently had diarrhoea or vomited
• you blood pressure is not sufficiently lowered due to ethnic affiliation (particularly in patients with black skin colour)

Taking other medicines
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 tert-butyramine if you are taking:
• medicines for high blood pressure including water tablets (diuretics)
• medicines for diabetes (insulin or tablets)
• for eye and skin conditions (eg. rheumatoid arthritis)
• the blood vessels. This makes it easier for your heart to pump blood through the body.

Perindopril tablets are not recommended for use in children and adolescents.

Perindopril 8mg 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 as a condition when 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 2mg tablets are used to:
• treat high blood pressure (hypertension)
• help to control the blood pressure of your body
• also reduce the risk of cardiac events, such as heart attack, in patients with stable coronary artery disease as a condition when 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.

Further information.

Perindopril 2mg, 4mg & 8mg Tablets
Perindopril tert-butyramine

W IL - UK

Perindopril 2mg, 4mg & 8mg PIL - UK

Approved for print date: 10/10/12

dimensions: 170 x 235
pharmacode: min pl size: 7pts

Technical Approval
date sent: 10/10/12
approved: 10/10/12

Pharmaceuticals
Continued over page
How to take Perindopril tablets

Your doctor will decide on the amount of perindopril tablets you should start to take. This may be increased depending on your condition and other medicines you are taking. Always take Perindopril tert-butylamine 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 tert-butylamine may be used in more than one way, or with other medicines which lower blood pressure.

- Take Perindopril tablets by mouth.
- Take them in the morning, before a meal.
- It's best to take your tablets with a glass of water at the same time each day.

Perindopril tert-butylamine is not for use in children and adolescents.

The usual dose is:

- High blood pressure:
  - Starting dose: 4mg Perindopril tert-butylamine each day
  - After a month, this may be raised to 4mg each day.
  - Each day: the highest amount usually needed.

- In older people with high blood pressure: the daily amounts are usually:
  - 2mg each day
  - After a month, this may be raised to 4mg each day.

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

If you can't take water tablets (diuretics):
- your doctor may stop them 2 to 3 days before you start taking Perindopril tert-butylamine.
- This is to help to avoid a low blood pressure.
- If needed, you can start taking water tablets again after you have started Perindopril tert-butylamine.
- It is not possible to stop your water tablets, then you can take 2mg of perindopril tert-butylamine as well.

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

The doctor may start you with 2mg perindopril tert-butylamine if:
- you do not have enough water in your body (dehydration).
- you have a low level of salt in your blood.
- you have a heart problem which means that this fluid is failing to pump 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).
- you have an excessive drop in blood pressure following the initial dose.

Heart failure:
- The strength of the pulse is not suitable for treatment of this condition.
- Starting dose 2mg Perindopril tert-butylamine each day.
- After 2 weeks, this may be raised to 4mg each day.

Stable coronary artery disease:
- The usual starting dose is 4mg Perindopril tert-butylamine once daily.
- After two weeks, this may be raised to 8mg each day.

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

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

If you take more perindopril tert-butylamine than you should:
- Immediately contact your doctor or 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, hot headache, uneven heartbeat (palpitations), slow heartbeat, feeling dizzy or nervous and rough.

The most likely effect in case of overdose is low blood pressure which can make you feel dizzy or faint. If this happens, bring down the dose with your legs raised.

If you forget to take perindopril tert-butylamine:
- 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 tert-butylamine:
- Do not stop taking Perindopril tablets 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 tablets your condition may get worse.
- If you have any further questions on the use of this product, ask your doctor or pharmacist.

Possible Side Effects

Like all medicines, perindopril tert-butylamine 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
- kidney problems
- uneven heartbeat
- sweating
- feeling very unwell.

In rare cases, a very serious reaction called angioedema, which can happen with all medicines of the type (ACE inhibitors), you must get treatment immediately, usually in hospital.

Common (affecting 1 or more in 100 but less than 1 in 10 patients):
- cough
- common colds
- infections
- skin reaction
- unusual tiredness or weakness
- very rare (affecting less than 1 in 10,000 patients):
- Angioedema
- swelling of the face, lips, mouth, tongue or throat
- swelling of the skin
- feeling very unwell
- change in mood or sleep
- fever
- taste change in the mouth
- vomiting
- diarrhoea
- abnormal bleeding

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

Further information

What Perindopril tablets contain

Perindopril tert-butylamine is an ingredient in Perindopril tablets. Each Perindopril 2mg tablet contains 2mg of perindopril tert-butylamine salt equivalent to 1.669mg of perindopril.

Each Perindopril 4mg tablet contains 4mg of perindopril tert-butylamine salt equivalent to 3.336mg of perindopril.

Each Perindopril 8mg tablet contains 8mg of perindopril tert-butylamine salt equivalent to 6.671mg of perindopril.

Other ingredients are:
- Hydroxypropylcellulose, microcrystalline cellulose, lactose and magnesium stearate.

What Perindopril tablets look like and contents of the pack

4 mg:
- Tablet:
  - White, oblong tablets with a break line on both sides
  - 2mg: White, round, biconvex tablets, plain on both sides.

What to do if you take too much Perindopril tablets

- 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 stop the tablets and tell your doctor if you have forgotten. Contact your doctor if in doubt.
- Do not stop taking Perindopril tablets without talking to your doctor.
- Do not stop taking Perindopril tablets without talking to your doctor.
- If you have any further questions on the use of this product, ask your doctor or pharmacist.

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

Common (affecting 1 or more in 100 but less than 1 in 10 patients):
- cough
- common colds
- infections
- skin reaction
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- very rare (affecting less than 1 in 10,000 patients):
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Other ingredients are:
- Hydroxypropylcellulose, microcrystalline cellulose, lactose and magnesium stearate.

What Perindopril tablets look like and contents of the pack

2mg White, round, becomes tablets, plain on both sides
- 4mg White, oblong tablets with a break line on both sides, 2mg on one side and 4mg on the other
- 8mg White, round, becomes tablets with 2mg on one side and 4mg on the other

Each strength of tablet is available in packaging containing 14, 28, 30, 60, 90 and 180 tablets and an associated packaging.

All packs sizes may be marketed.

Marketing Authorisation holder and Manufacturer

Marketing Authorisation holder

Actavis Group PTC, OFC Reykjavikurvegur 76-78, 220 Hafnarfjörður, Iceland

Manufacturers
- Actavis Ireland Limited, 1 Howard Road, Eton Sources, Ballycoolin, Dublin 18, Ireland
- Glenmark Pharmaceuticals Ltd, Fibichova 143, 566 17 Vysoké Mýto, Czech Republic
- Actavis (Ireland) C/O, 13741 UI, Nieuw, The Netherlands
- Actavis Group PTC, OFC Reykjavikurvegur 76-78, 220 Hafnarfjörður, Iceland

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Perindopril 2mg, 4mg & 8mg PIL - UK

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