

## PACKAGE LEAFLET: INFORMATION FOR THE USER

---

### PRENESSA

2mg Tablets; 4mg Tablets; 8mg Tablets

PERINDOPRIL

---

*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •*

---

#### What is in this leaflet?

1. What PRENESSA is and what it is used for
2. Before you take PRENESSA
3. How to take PRENESSA
4. Possible side effects
5. How to store PRENESSA

#### 1. WHAT PRENESSA IS AND WHAT IS IT 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.

PRENESSA 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.

#### 2. BEFORE YOU TAKE PRENESSA

##### **Do not take PRENESSA Tablets**

- if you are allergic (hypersensitive) to perindopril or any of the other ingredients of PRENESSA Tablets or to any other ACE inhibitor.

- if you have had symptoms such as wheezing, swelling of the face, tongue or throat, intense itching, skin rash, fainting or feeling dizzy.

If you have had these symptoms when you have taken an ACE inhibitor in the past or at any other time, this may be angioedema. If so, do not take PRENESSA Tablets.

- if you are more than 3 months pregnant (It is also better to avoid PRENESSA Tablets 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 any of the above applies to you, talk to your doctor and do not take PRENESSA Tablets.

### **Warnings and precautions**

*Talk to your doctor before taking PRENESSA Tablets 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 problem,
- if you have kidney problems or if you receiving dialysis,
- if you suffer from a collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma,
- if you have diabetes,
- if you have been told to limit the salt in your diet or to use a salt-substitute containing potassium,
- if you are to undergo anaesthesia 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 effect of an allergy to bee or wasp stings,
- if you have recently suffered from diarrhoea or vomiting or are dehydrated,
- if you are of black origin since you may have higher risk of angioedema and this medicine may be less effective in lowering your blood pressure than in non-black patients.
- if you have been told by your doctor that you have an intolerance to some sugars,
- if you 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 PRENESSA Tablets”

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).

### **Children and adolescents**

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

### **Other medicines and PRENESSA Tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor may need to change your dose and/or to take other precautions:

If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take PRENESSA Tablets” and “Warnings and precautions”).

***In particular, talk to your doctor before taking PRENESSA Tablets if you are taking:***

- medicines for high blood pressure including aliskiren, 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,
- potassium-sparing drugs used in the treatment of heart failure: eplerenone and spironolactone at doses between 12.5 mg to 50 mg per 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 or metformin),
- baclofen (used to treat muscle stiffness in disease such as multiple sclerosis),
- medicines to treat mental disorder such as depression, anxiety, schizophrenia etc (e.g. tricyclic antidepressant, antipsychotics),
- immunosuppressant (medicines which reduce the defence mechanism of the body) used for the treatment of auto-immune disorder or following transplant surgery (e.g. ciclosporin, tacrolimus),
- trimethoprim (for the treatment of infections),
- estramustine (used in cancer therapy),
- 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),
- heparin (medicines used to thin blood),
- medicines used to treatment of low blood pressure, shock or asthma (e.g. ephedrine, nor adrenaline or adrenaline),
- gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis).

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.

***Taking PRENESSA Tablets with food and drink***

Drinking alcohol with PRENESSA Tablets may make you feel dizzy. Check with your doctor whether you can drink alcohol when taking this medicine.

Take your PRENESSA Tablets in the morning before a meal.

***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 PRENESSA Tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of

PRENESSA Tablets. 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. PRENESSA Tablets are 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.

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

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

### ***Important information about some of the ingredients of PRENESSA Tablets***

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 medicinal product.

### ***Information on special patient groups***

PRENESSA Tablets should not be given to children.

## ***3. HOW TO TAKE PRENESSA***

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 PRENESSA Tablets 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 PRENESSA 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.

The usual dose is:

#### ***High blood pressure:***

- 4 mg 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 **65 or 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.

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

- your doctor may stop them 2 to 3 days before you start taking PRENESSA Tablets. This is to prevent a fall in your blood pressure.
- if needed, you can start taking water tablets again after you have started Perindopril Tablets.
- if it is not possible to stop your water tablets, then you can take 2 mg of perindopril as well.
- Your doctor or pharmacist will tell you exactly what you should do.

The doctor may **start you with 2 mg perindopril** if:

- your blood pressure is very high
- you have not 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).

**Heart failure:**

- 2 mg each day to start
- after 2 weeks, this may be raised to 4 mg each day, which is the maximum recommended dose for heart failure.

**Stable coronary artery disease:**

- the usual starting dose is 4 mg once daily
- after two weeks, this may be raised to 8 mg each day, which is the maximum recommended dose in this condition.

**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. The dose should be increased only if the previous lower dose is well tolerated.

**Paediatric use:** Use in children is not recommended.

**If you take more PRENESSA Tablets than you should**

Talk to a doctor or pharmacist straight away or contact your nearest accident and emergency department.

The following effects may happen:

Shock, kidney problems, fast breathing, fast heartbeat, uneven heartbeat (palpitations), slow heartbeat, feeling dizzy or anxious, 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 PRENESSA Tablets**

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

### ***If you stop taking PRENESSA Tablets***

Do not stop taking PRENESSA 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 PRENESSA Tablets 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 everybody 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
- severe abdominal pain

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 (may affect upto 1 in 10 people):**

Headache, dizziness, vertigo, pins and needles, vision disturbance, tinnitus, (sensation of noise in the ears), light-headedness due to low blood pressure, cough, shortness of breath, gastro-intestinal disorder (nausea, vomiting, abdominal pain, taste disturbances, dyspepsia or difficulty of digestion, diarrhoea, constipation), allergic reaction (such as skin rashes, itching), muscle cramps, feeling of tiredness,

#### **Uncommon (may affect up to 1 in 100 people):**

- Mood swings, sleep disturbances, bronchospasm (tightening of the chest, wheezing and shortness of breath), dry mouth, angioedema (symptoms such as wheezing, swelling of the face, tongue or throat), intense itching or severe skin rashes, formation of blister clusters over the skin, kidney problems, impotence, sweating, an excess of eosinophils (a type of white blood cells), somnolence, fasting, palpitations, tachycardia, vasculitis (inflammation of blood vessels), photosensitivity reaction (increased sensitivity of skin to sun), arthralgia (joint pain), myalgia (muscle 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 (may affect up to 1 in 1000 people):**

- Change in laboratory parameters: Increased level of liver enzymes, high level of serum bilirubin.

#### **Very rare (may affect up to 1 in 10,000 people):**

- confusion, cardiovascular disorder (irregular heartbeat, heart attack and stroke), eosinophilic pneumonia (a rare type of pneumonia), rhinitis (blocked up or runny nose), erythema multiforme, acute renal failure, change in blood value such as lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets, inflammation of the pancreas (which causes severe pain in the abdomen and the back), hepatitis.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicines.

**5. HOW TO STORE PRENESSA**

- Keep this medicine out of the sight and reach of children.
- Store below 25°C and in the original package

**Use-by date**

Do not use PRENESSA Tablets after the expiry date which is stated on the packet after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.