

Package leaflet: Information for the user

Eprosartan 300mg Film-coated Tablets

Eprosartan 400mg Film-coated Tablets

Eprosartan 600mg Film-coated Tablets

eprosartan mesilate

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

1. What Eprosartan is and what it is used for

Eprosartan 300mg, 400mg and 600mg film-coated tablets contains a medicine called eprosartan mesilate. This belongs to a group of medicines called 'angiotensin II receptor antagonists'.

This medicine is used to treat high blood pressure, also called hypertension.

The main cause of high blood pressure is narrowing of the blood vessels. This increases the amount of work your heart must do to pump blood around your body. You may not feel unwell, but if high blood pressure is not treated, it can lead to heart disease and stroke.

How Eprosartan works:

- Angiotensin II is a chemical found in the body which makes your blood vessels contract. This makes it more difficult for blood to pass through them
- This causes your blood pressure to rise
- Eprosartan works by preventing the chemical, angiotensin II, from causing your blood vessels to contract. This has the effect of lowering your blood pressure.

You may be given Eprosartan on its own or with another medicine used to treat high blood pressure. Using both medicines together will lower your blood pressure more than one on its own.

The active ingredient in this medicine is eprosartan mesilate. This is the new name for eprosartan mesylate. The active ingredient itself has not changed.

2. What you need to know before you take Eprosartan

Do not take Eprosartan:

- if you are allergic (hypersensitive) to eprosartan or any of the other ingredients of this medicine (listed in section 6 below)
- if you have severe liver problems
- if you are more than 3 months pregnant (it is also better to avoid Eprosartan in early pregnancy - see "Pregnancy breast-feeding and fertility" section)
- if you have damaged blood flow to the kidneys or serious constrictions in a single functioning kidney
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Do not take Eprosartan if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Eprosartan if:

- You have heart, kidney or liver problems, especially severe heart failure, narrowing of the heart valves, thickening of heart muscle (hypertrophic cardiomyopathy)
- You have narrowing or a blockage of the blood vessels leading to your kidneys or if you only have one kidney
- You have recently been sick or had diarrhoea
- You are taking water tablets (diuretics) and they make you feel dizzy when you stand up
- You are taking water tablets or potassium supplements and you also have a kidney problem. Your doctor might sometimes check your blood to make sure that Eprosartan is not affecting the amount of potassium in your blood
- You suffer from lactose intolerance (see section 'Eprosartan contains lactose')
- You think you are (or might become) pregnant. Eprosartan 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, breast-feeding and fertility section")
- You have been told you have Conn's syndrome (primary hyperaldosteronism) i.e. your body is making too much of the hormone aldosterone. Eprosartan may not work, so check with your doctor
- You are taking medicines to treat high blood pressure such as aliskiren or an ACE-inhibitor (for example enalapril, lisinopril, ramipril), particularly if you have diabetes-related kidney problems
- You experience abdominal pain, nausea, vomiting or diarrhoea after taking Eprosartan. Your doctor will decide on further treatment. Do not stop taking Eprosartan on your own.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals. If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Eprosartan. See also Section 2 of this leaflet under the heading "Do not take Eprosartan".

Other medicines and Eprosartan

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. Your doctor may need to change your dose and/or to take other precautions.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines for pain and inflammation such as ibuprofen, diclofenac, celecoxib, etoricoxib or lumiracoxib (Non-steroidal anti-inflammatory medicines)
- Potassium supplements, potassium-sparing agents or potassium-containing salt substitutes
- Medicines that increase potassium levels such as heparin
- Water tablets (Diuretics) such as hydrochlorothiazide and calcium channel blocker such as nifedipine which may be used to help lower your blood pressure
- Aspirin (more than 3g per day) used for pain, fever and to prevent blood clotting
- Lithium used for mental problems
- ACE-inhibitors or aliskiren (See also Section 2 of this leaflet under the headings "Do not take Eprosartan" and "Take special care with Eprosartan").

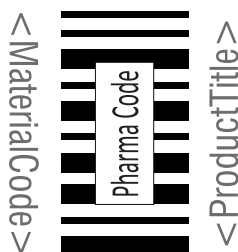
If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Eprosartan.

Pregnancy, breast-feeding and fertility

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will normally advise you to stop taking Eprosartan before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Eprosartan. Eprosartan 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.

Continued overleaf



Breast-feeding

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

You may feel tired or dizzy when you start taking Eprosartan. If this happens, do not drive or use any tools or machines until these effects wear off.

Eprosartan contains lactose:

Eprosartan contains lactose (a type of sugar). 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 Eprosartan

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

Taking this medicine

- Your doctor will tell you how many tablets to take and for how long. It is important that you keep taking the tablets for as long as your doctor tells you
- The pharmacist's label on your pack will also tell you how much your doctor would like you to take. Please read it carefully
- Only remove a tablet from the blister strip when it is time to take your medicine
- Take your tablet with or without food
- Take your tablets at about the same time each day.

Adults aged under 75 years

- The usual starting dose is 600mg once a day
- Your doctor may increase your daily dose to 800mg (two 400mg tablets).

Elderly people (aged 75 or over) and people with kidney or liver problems

- No dose adjustment is required in elderly people
- If you have liver or kidney problems, consult your doctor. Your doctor will decide your daily dosage.

Use in children and adolescents

Eprosartan should not be used in children and adolescents under 18 years of age.

If you take more Eprosartan than you should

If you take more Eprosartan than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Eprosartan

- If you forget to take a dose, take it as soon as you remember
- Take your next dose at the normal time
- Do not take two doses within 12 hours of each other.

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

If you stop taking Eprosartan

Keep taking this medicine until your doctor tells you to stop. Do not stop taking Eprosartan just because you feel better.

4. Possible side effects

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

Stop taking Eprosartan and see a doctor straight away if you develop any of the following symptoms - you may need urgent medical treatment:

- Sudden swelling of your face, lips or tongue and breathing problems. These may be signs of a severe allergic reaction and may be life threatening. This side effect is uncommon (*at least 1 in 1000 and less than 1 in 100 patients*).

A list of possible side effects reported in clinical studies with eprosartan is given below:

Very common (*at least 1 in 10 patients or more*):

- Headache

Common (*at least 1 in 100 and less than 1 in 10 patients*):

- Skin rashes or itching
- Weakness or lack of strength
- Feeling dizzy

- Feeling or being sick (nausea or vomiting)
- Diarrhoea
- Runny nose

Uncommon (*at least 1 in 1000 and less than 1 in 100 patients*):

- Low blood pressure (hypotension)
- Sudden swelling of your face, lips or tongue and breathing problems. These may be signs of a severe allergic reaction and may be life threatening

Undesirable effects have been reported since Eprosartan has been marketed but the frequency is not known

- Changes in kidney function including kidney failure in patients with existing kidney problems
- Pain in a joint
- Intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting, and diarrhoea has been reported after the use of similar products.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Eprosartan

Keep this medicine out of the sight and reach of children.

Do not use Eprosartan after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month. Do not use Eprosartan if you notice any visible signs of deterioration. 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.

6. Contents of the pack and other information

What Eprosartan contains:

The active substance is eprosartan (as mesilate). Each tablet contains 300mg, 400mg or 600mg of eprosartan. The other ingredients are: lactose, microcrystalline cellulose (E460), magnesium stearate (E572), croscarmellose sodium, hydroxypropylcellulose, hypromellose, titanium dioxide (E171), polysorbate 80 (E433) and macrogol 400.

- The 300mg and 600mg tablets also contain opadry white 13B58894
- The 400mg tablets also contain iron oxides (E172) and opadry pink 13B84595.

What Eprosartan looks like and contents of the pack

300mg: White to off-white, oval shaped, biconvex film-coated tablets debossed with 'I' on one side and '120' on other side.

400mg: Pink, oval shaped, biconvex film-coated tablets debossed with 'I' on one side and '121' on other side.

600mg: White to off-white, modified capsule shaped, biconvex film-coated tablets debossed with 'H' on one side and '188' on other side.

Eprosartan is available in blister packs containing 28 or 56 tablets.

Marketing Authorisation Holder and Manufacturer

MA Holder

Manx Healthcare Ltd
Unit 2, Bosworth Avenue, Tournament Fields, Warwick, CV34 6UQ, UK

Manufacturer

Pharmadox Healthcare Ltd
KW20A Kordin Industrial Park, Paola, PLA 3000, Malta
or

Manx Healthcare Ltd
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Other formats

To request a copy of this leaflet in Braille, large print or audio, please call 01926 482511.

This leaflet was last revised in January 2025

URN: GEP01-PIL-10-070125

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