

## PACKAGE LEAFLET: INFORMATION FOR THE USER

**Eprosartan Teva 300 mg Film-coated Tablets**

**Eprosartan Teva 400 mg Film-coated Tablets**

**Eprosartan Teva 600 mg Film-coated Tablets**

Eprosartan

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

#### **1. What Eprosartan Teva is and what it is used for**

Eprosartan Teva contains the active substance eprosartan.

Eprosartan belongs to a group of medicines called ‘angiotensin II receptor antagonists’. It blocks the action of a substance in your body called ‘angiotensin II’. This substance causes your blood vessels to narrow. This makes it more difficult for the blood to flow through the vessels and so your blood pressure increases. By blocking this substance, the vessels relax and your blood pressure decreases.

Eprosartan is used to treat high blood pressure (hypertension).

#### **2. What you need to know before you take Eprosartan Teva**

##### **Do not take Eprosartan Teva:**

- if you are allergic to eprosartan or any of the other ingredients of this medicine (listed in Section 6).
- if you have **severe** liver disease.
- if you have **severe** problems with the blood flow in your kidneys or serious restriction to blood flow in a single functioning kidney.
- if you are more than 3 months pregnant (it is also better to avoid eprosartan 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.

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 eprosartan.

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Eprosartan Teva.

Check with your doctor or pharmacist before taking this medicine if:

- you have any other liver problems

- you have any other kidney problems. Your doctor will check how well your kidneys are working before you start your treatment and at intervals during your treatment. Your doctor will also check the potassium, 'creatinine' and 'uric acid' levels in your blood.
- you have a heart problem such as coronary heart disease, heart failure, a narrowing of your blood vessels or heart valves, or a problem with your heart muscle.
- you produce too much of a hormone called 'aldosterone'.
- you are on a low-salt diet, taking 'water tablets' or are being sick or have diarrhoea. This is because they may cause your blood volume or the sodium level in your blood to decrease. These should be corrected before starting treatment with Eprosartan Teva.
- you know you have raised potassium levels in your blood.
- you think you are (or might become) pregnant. Eprosartan Teva 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.
- you are taking any of the following medicines used to treat high blood pressure:
  - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), 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 Eprosartan Teva.

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

### **Children and adolescents**

Children and adolescents under 18 years should not take eprosartan.

### **Other medicines and Eprosartan Teva**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Eprosartan Teva can affect the way some other medicines work. Also some other medicines can affect the way Eprosartan Teva works.

### **In particular, tell your doctor or pharmacist if you are taking the following:**

- lithium – for mood problems. Your doctor must monitor the lithium level in your blood because Eprosartan may increase the level.
- Medicines for pain and inflammation such as ibuprofen, diclofenac, celecoxib, etoricoxib or lumiracoxib (non-steroidal anti-inflammatory medicines).

### **The following medicines may increase the effect of Eprosartan Teva:**

- medicines that lower your blood pressure.

### **The following medicines may decrease the effect of Eprosartan Teva:**

- indometacin – for pain, stiffness, swelling and lowering a high temperature.

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

### **If you are taking any of the following medicines your doctor may carry out blood tests:**

- medicines containing potassium or potassium-sparing medicines.
- medicines that increase potassium levels such as 'heparin' and 'ACE inhibitors'.

Talk to your doctor or pharmacist before taking Eprosartan Teva. Depending on the outcome of your blood tests, your doctor may decide to change your treatment with these medicines or Eprosartan Teva.

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

- If you are taking an ACE-inhibitor or aliskiren (see also information under the headings 'Do not take Eprosartan Teva' and 'Warnings and precautions').

**Eprosartan Teva with food and drink**

- You can take the tablets with or without food.
- Speak to your doctor before taking Eprosartan Teva if you are on a low-salt diet. Not having enough salt may cause your blood volume or the sodium level in your blood to get lower.

**Pregnancy and breast-feeding****Pregnancy**

- You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Eprosartan Teva before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Eprosartan Teva.
- Eprosartan Teva is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant. It may cause serious harm to your baby if used after the third month of pregnancy.

**Breast-feeding**

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

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.

**Driving and using machines**

Eprosartan Teva is unlikely to affect your ability to drive or use tools and machines. However, you may feel sleepy or dizzy while taking Eprosartan Teva. If this happens, do not drive or use any tools or machines and talk to your doctor.

**Eprosartan Teva contains lactose (a type of sugar)**

If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

**3. How to take Eprosartan Teva**

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

**Adults**

The recommended dose is 600 mg eprosartan once daily.

**Use in children and adolescents**

Eprosartan Teva should not be given to children and adolescents aged under 18 years.

**Taking this medicine**

- Take this medicine by mouth
- Swallow the tablet whole with plenty of fluid, such as a glass of water
- Do not crush or chew the tablets
- Take the tablets in the morning at around the same time each day

**If you take more Eprosartan Teva than you should**

If you take more Eprosartan Teva than you should or someone accidentally takes some, talk to a doctor or go to a hospital straight away. Take the medicine pack with you. The following effects can happen:

- feeling light-headed and dizzy due to a fall in your blood pressure (hypotension)
- feeling sick (nausea)
- feeling sleepy

**If you forget to take Eprosartan Teva**

- If you forget a dose, take it as soon as you remember it.

- If you forget to take a dose and it is nearly time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Eprosartan Teva**

Do not stop taking Eprosartan Teva without talking to your doctor first.

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

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

#### **Allergic reactions** (may affect up to 1 in 100 people)

If you have an allergic reaction, stop taking and see a doctor straight away. The signs may include:

- skin reactions such as a rash or hives with swelling (urticaria)
- swelling of the lips, face, throat or tongue
- shortness of breath
- swelling of your face, swelling of skin and mucous membrane (angiodema)

#### **Other possible side effects of Eprosartan Teva include:**

**Very common:** may affect more than 1 in 10 people

- headache

**Common:** may affect up to 1 in 10 people

- viral infection
- raised fat (triglyceride) levels in the blood
- feeling dizzy, feeling unusually tired
- feeling depressed
- chest pain, palpitations (missed heart beats)
- back or joint pain
- urinary tract infection
- rash, itching and hives
- feeling sick, being sick, diarrhoea, stomach pain, indigestion
- feeling weak (asthenia)
- stuffy nose (rhinitis), sore or hoarse throat, breathlessness, cough, chest infection
- general pain

**Uncommon:** may affect up to 1 in 100 people

- low blood pressure. You may feel light-headed or dizzy
- too high potassium levels in the blood
- swelling under the skin
- allergic reaction

**Rare:** may affect up to 1 in 1000 people

- anaemia
- increased urea levels in the blood

**Not known:** frequency cannot be estimated from the available data

- loss of muscle tone and strength
- dizziness on standing up
- swelling of the face
- kidney problems, including kidney failure

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Eprosartan Teva

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

Do not use this medicine after the expiry date which is stated on the carton and blister foil after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Teva contains

The active substance is eprosartan (as mesilate). Each tablet contains either 300 mg, 400 mg or 600 mg of eprosartan.

The other ingredients are:

Tablet core: lactose monohydrate, microcrystalline cellulose, pregelatinised maize starch, silica colloidal anhydrous, povidone, polysorbate 80, crospovidone, magnesium stearate.

Film-coating: hypromellose, hydroxypropylcellulose (E463), titanium dioxide (E171), macrogol 400. The film-coating for the 400 mg tablets also contains yellow and red iron oxides (E172).

### What Eprosartan Teva looks like and contents of the pack

The 300 mg tablets are white, ovaloid shaped, biconvex film-coated tablets. The 400 mg tablets are peach-coloured, oval shaped, biconvex film-coated tablets. The 600 mg tablets are white, capsule shaped, biconvex film-coated tablets.

Eprosartan Teva tablets are available in aluminium blister packs containing 4, 7, 14, 28, 50, 56, 98 and 280 film-coated tablets.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

#### Marketing Authorisation Holder:

Teva B.V.  
Swensweg 5  
2031GA Haarlem  
The Netherlands

#### Manufacturer:

Niche Generics Limited, Unit 5, 151 Baldoyle Industrial Estate, Dublin 13

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

<b>Germany</b>	Eprosartan-ratiopharm 600 mg Filmtabletten
<b>Ireland</b>	Eprosartan Teva 300mg, 400 mg & 600 mg Film-

	coated Tablets
<b>Netherlands</b>	Eprosartan Teva 400 mg / 600 mg, filmomhulde tabletten
<b>United Kingdom</b>	Eprosartan 300 mg, 400 mg and 600 mg Film-coated Tablets

**This leaflet was last revised in March 2015**