

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **EPROSARTAN MYLAN 300 mg EPROSARTAN MYLAN 400 mg EPROSARTAN MYLAN 600 mg FILM-COATED TABLETS (eprosartan)**

**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 further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **IN THIS LEAFLET:**

1. What Eprosartan Mylan is and what it is used for
2. Before you take Eprosartan Mylan
3. How to take Eprosartan Mylan
4. Possible side effects
5. How to store Eprosartan Mylan
6. Further information.

#### **1. WHAT EPROSARTAN MYLAN IS AND WHAT IT IS USED FOR**

Eprosartan Mylan belongs to a family of medicines known as angiotensin II antagonists. Angiotensin II is produced in your body and causes blood vessels to become narrower. This makes the blood flow through the vessels more difficult and the blood pressure increases. Eprosartan blocks this action so that the blood vessels relax and the blood pressure is lowered.

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

#### **2. BEFORE YOU TAKE EPROSARTAN MYLAN**

**Do not take Eprosartan Mylan if:**

- you are allergic (hypersensitive) to eprosartan or any of the other ingredients in Eprosartan tablets
- you are more than 3 months pregnant. (It is also better to avoid Eprosartan in early pregnancy – see pregnancy section.)
- you have severe liver problems
- you have damaged blood flow to the kidneys or serious constrictions in a single functioning kidney
- 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 Mylan

- if you think that 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 section)
- if you are dehydrated, have low salt levels because you are on a low salt diet or are taking water tablets or you have diarrhoea or vomiting. These conditions should be corrected before you start taking Eprosartan.
- if you know you have raised potassium levels in your blood
- if you suffer from heart disease eg. heart valve disease, or an enlarged heart
- if you have severe kidney problems, have had a kidney transplant or need dialysis

- if you have narrowing or a blockage of the blood vessels leading to your kidneys or if you only have one kidney
- if you have liver problems
- if you have a condition affecting your adrenal gland (hyperaldosteronism)
- if you are black, taking Eprosartan may be less effective in lowering the blood pressure
- if you are taking any other 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”

### **Other medicines and Eprosartan**

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, or the following:

- other blood pressure lowering medicine
- potassium supplements, potassium-sparing agents or potassium-containing salt substitutes
- a diuretic (‘water tablet’) and calcium channel blockers eg. sustained – release nifedipine
- heparin, used to treat blood clots
- supplements or salt substitutes containing potassium
- lithium, used to treat certain mental disorders
- medicines for pain and inflammation such as ibuprofen, diclofenac, celecoxib, etoricoxib or lumiracoxib (Non-steroidal anti-inflammatory medicines)
- aspirin (more than 3 g per day) used for pain, fever and to prevent blood clotting

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

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

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

### **Taking Eprosartan Mylan with food and drink**

This medicine can be taken with or without food.

### **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 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.

### **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.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

There is no information available to suggest Eprosartan affects your ability to drive or use machines. However, Eprosartan may cause side effects in some patients such as feeling tired or dizziness. Do not drive or operate machines if your ability to drive or use machines is affected.

### **Important information about some of the ingredients of Eprosartan Mylan**

This medicine contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, **such as lactose**, contact your doctor before taking this medicine.

### **3. HOW TO TAKE EPROSARTAN MYLAN**

Always take Eprosartan exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow the tablets whole with water once a day, with or without food. Try to take your tablets at the same time each day.

#### **Adults**

The usual starting dose is 600 mg of Eprosartan once a day.

Eprosartan may be used alone or along with other medicine eg. a diuretic, to help lower your blood pressure.

#### **Children**

Children and adolescents under 18 years should not take Eprosartan.

**Patients with liver or kidney problems** - Do not take Eprosartan if you have severe liver problems (see section 2, 'Do not take Eprosartan if:'). If you have kidney problems, your doctor may give you a lower dose.

**If you take more Eprosartan than you should:** Contact your doctor or nearest hospital emergency department **immediately**. Remember to take the container and any remaining tablets with you. Symptoms of overdose include low blood pressure resulting in dizziness especially when getting up from a sitting or lying position.

**If you forget to take a dose of Eprosartan:** Take the next dose as soon as you remember unless it is almost time for your next dose. **Do not** take two doses within 12 hours of each other or take a double dose to make up for a forgotten dose. If you miss several doses, contact your doctor.

**If you suddenly stop taking Eprosartan:** Your blood pressure may increase. Speak to your doctor first before stopping this medicine.

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

### **4. POSSIBLE SIDE EFFECTS**

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

**If any of the following happen, stop taking Eprosartan and tell your doctor immediately or go to your nearest hospital emergency department you may need urgent medical treatment:**

- itchy swollen skin, skin rash
- feeling short of breath or wheezy
- swelling of the face, lips, tongue and/or throat.

These may be signs of a severe allergic reaction which could be life threatening.

A list of possible side effects and their frequency that were reported in clinical studies is given below:

**Very common side effects** (affects more than 1 user in 10)

- headache

**Common side effects** (affects 1 to 10 users in 100)

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

**Uncommon side effects** (affects 1 to 10 users in 1,000)

- too much potassium levels in the blood.
- swelling under the skin
- low blood pressure
- allergic reaction

**Rare side effects** (affects 1 to 10 users in 10,000)

- anaemia
- increase in urea levels in the blood.

**Not known side effects** (frequency cannot be estimated from the available data):

- loss of muscle tone and strength
- dizziness on standing up
- swelling of the face

The following additional side effects were reported by the market:  
Changes in kidney function, including renal failure, in patients at risk.

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

**5. HOW TO STORE EPROSARTAN MYLAN**

Keep out of the reach and sight of children.

Do not take Eprosartan Mylan after the expiry date stated on the carton, blister or bottle after EXP. The expiry date refers to the last day of that month.

There are no special storage requirements for this medicine.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. FURTHER INFORMATION**

**What Eprosartan Mylan contains**

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

The other ingredients are:

Tablet core - lactose monohydrate, pregelatinized maize starch, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate, polysorbate 80, povidone K-12, crospovidone Type B.

Film-coating – hydroxypropyl cellulose (E462), hypromellose 6 cP, titanium dioxide (E171), macrogol 400. The film-coating for the 400 mg tablets also contains yellow and red iron oxides (E172).

Printing ink – shellac, black iron oxide (E172), ammonium hydroxide 28 %, propylene glycol

What Eprosartan Mylan looks like and contents of the pack

The 300 mg tablets are off-white oval tablets marked 'M EN1' on one side. The 400 mg tablets are pink, capsule-shaped tablets marked 'M EN2' on one side. The 600 mg tablets are off-white capsule-shaped tablets marked 'M EN3' on one side only.

Eprosartan Mylan Tablets are available in HDPE bottles containing 500 film-coated tablets and aluminium blister packs containing 14, 28, 30, 56, 98, 100 and 168 film-coated tablets. Calendar pack sizes of 14, 28, 56, 98 and 168 film-coated tablets.

Not all pack sizes and presentation may be marketed

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

McDermott Laboratories Limited t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Mylan Hungary Kft., H-2900, Komárom, Mylan útca.1, Hungary

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

Belgium	Eprosartan Mylan 600 mg filmomhulde tabletten
Denmark	Eprosartan Mylan 600 mg
Finland	Eprosartan Mylan 600 mg
Germany	Eprosartan Mylan 300 mg, 400 mg and 600 mg Filmtabletten
Ireland	Eprosartan Mylan 300 mg, 400 mg and 600 mg Film-coated tablets
Italy	Eprosartan Mylan Generics 300 mg, 400 mg and 600 mg
The Netherlands	Eprosartan Mylan 300 mg, 400 mg and 600 mg filmomhulde tabletten
Norway	Eprosartan Mylan 600 mg
Portugal	Eprosartan Mylan 400 mg and 600 mg Comprimido revestido por película
Romania	Eprosartan Generics 300 mg, 400 mg and 600 mg comprimate filmate
Slovak Republic	Eprosartan Mylan 600mg Filmom obalená tableta
Spain	Eprosartán Mylan 600 mg comprimidos recubiertos con película EFG
United Kingdom	Eprosartan Mylan 300 mg, 400 mg and 600 mg Film-coated tablets

**This leaflet was last approved in July 2014**