

## PACKAGE LEAFLET: INFORMATION FOR THE USER

**Losartan Mylan 12.5 mg Film-Coated Tablets**

**Losartan Mylan 50 mg Film-Coated Tablets**

**Losartan Mylan 100 mg Film-Coated Tablets**

losartan potassium

**Read all of this leaflet carefully before taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your 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 Losartan Mylan is and what it is used for
2. Before you take Losartan Mylan
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4. Possible side effects
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### **1. WHAT LOSARTAN MYLAN IS AND WHAT IT IS USED FOR**

Losartan Mylan belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body, which binds to receptors in blood vessels, causing them to tighten. This results in an increase in blood pressure. Losartan Mylan prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax which in turn lowers the blood pressure. Losartan Mylan slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Losartan Mylan is used:

- to treat patients with high blood pressure (hypertension) in adults and in children and adolescents 6-18 years of age.
- to protect the kidney in hypertensive type 2 diabetic patients with laboratory evidence of impaired renal function and proteinuria  $\geq 0.5$  g per day (a condition in which urine contains an abnormal amount of protein).
- to treat patients with chronic heart failure when therapy with specific medicines called angiotensin-converting-enzyme inhibitors (ACE inhibitors, medicine used to lower high blood pressure) is not considered suitable by your doctor. If your heart failure has been stabilised with an ACE inhibitor you should not be switched to losartan potassium.
- in patients with high blood pressure and a thickening of the left ventricle, losartan potassium has been shown to decrease the risk of stroke ("LIFE indication").

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

**Do NOT take Losartan Mylan:**

- if you are allergic (hypersensitive) to losartan potassium or to any of its other ingredients
- if your liver function is severely impaired
- if you are more than 3 months pregnant. (It is also better to avoid Losartan Mylan 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

### **Take special care with Losartan Mylan:**

You must tell your doctor if you think you are (or might become) pregnant. Losartan Mylan 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).

### **It is important to tell your doctor before taking Losartan Mylan:**

- if you have had a history of angio-oedema (swelling of the face, lips, throat, and/or tongue) (see also section 4 'Possible side effects'),
- if you suffer from excessive vomiting or diarrhoea leading to an extreme loss of fluid and/or salt in your body,
- if you receive diuretics (medicines that increase the amount of water that you pass out through your kidneys) or are under dietary salt restriction leading to an extreme loss of fluid and salt in your body (see section 3 'Dosage in special patient groups'),
- if you are known to have narrowing or blockage of the blood vessels leading to your kidneys or if you have received a kidney transplant recently,
- if your liver function is impaired (see sections 2 "Do not take Losartan Mylan " and 3 'Dosage in special patient groups'),
- if you suffer from heart failure with or without renal impairment or concomitant severe life threatening cardiac arrhythmias. Special caution is necessary when you are treated with a  $\beta$ -blocker concomitantly,
- if you have problems with your heart valves or heart muscle,
- if you suffer from coronary heart disease (caused by a reduced blood flow in the blood vessels of the heart) or from cerebrovascular disease (caused by a reduced blood circulation in the brain),
- if you suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone by the adrenal gland, caused by an abnormality within the gland).
- if 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 Losartan Mylan".

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or herbal medicines and natural products. Take particular care if you are taking the following medicines while under treatment with Losartan Mylan:

- other blood pressure lowering medicines as they may additionally reduce your blood pressure. Blood pressure may also be lowered by one of the following drugs/ class of drugs: tricyclic antidepressants, antipsychotics, baclofen, amifostine,
- medicines which retain potassium or may increase potassium levels (e.g. potassium supplements, potassium-containing salt substitutes or potassium-sparing medicines such as certain diuretics [amiloride, triamteren, spironolactone] or heparine),

- non-steroidal anti-inflammatory drugs such as indomethacin, including cox-2-inhibitors (medicines that reduce inflammation, and can be used to help relieve pain) as they may reduce the blood pressure lowering effect of Losartan Mylan.

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 Losartan Mylan” and “Warnings and precautions”).

If your kidney function is impaired, the concomitant use of these medicines may lead to a worsening of the kidney function.

Lithium containing medicines should not be taken in combination with losartan potassium without close supervision by your doctor. Special precautionary measures (e.g. blood tests) may be appropriate.

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

Losartan Mylan may be taken with or without food.

### **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 Losartan Mylan before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Losartan Mylan.

Losartan Mylan 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. Losartan Mylan 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.

### **Use in children and adolescents**

Losartan Mylan has been studied in children. For more information, talk to your doctor.

### **Driving and using machines**

No studies on the effects on the ability to drive and use machines have been performed.

Losartan Mylan is unlikely to affect your ability to drive or use machines. However, as with many other medicines used to treat high blood pressure, Losartan Mylan may cause dizziness or drowsiness in some people. If you experience dizziness or drowsiness, you should consult your doctor before attempting such activities.

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

Losartan Mylan Tablets contain lactose monohydrate. 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 LOSARTAN MYLAN**

Always take Losartan Mylan exactly as your doctor has instructed you. Your doctor will decide on the appropriate dose of Losartan Mylan, depending on your condition and whether you are taking other medicines.

It is important to continue taking Losartan Mylan for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

#### Adult patients with High Blood Pressure

Treatment usually starts with 50 mg losartan potassium (one Losartan Mylan 50 mg Film-Coated Tablet) once a day. The maximal blood pressure lowering effect should be reached 3-6 weeks after beginning treatment. In some patients the dose may later be increased to 100 mg losartan potassium (two tablets Losartan Mylan 50 mg Film-Coated Tablets) once daily.

If you have the impression that the effect of losartan potassium is too strong or too weak, please talk to your doctor or pharmacist.

#### Use in children or adolescents (6 to 18 years old)

The recommended starting dose in patients who weigh between 20 and 50 kg is 0.7 mg of losartan potassium per kg of body weight administered once a day (up to 25 mg of Losartan Mylan). The doctor may increase the dose if blood pressure is not controlled.

#### Adult patients with high blood pressure and Type 2 diabetes

Treatment usually starts with 50 mg losartan potassium (one Losartan Mylan 50 mg Film-Coated Tablet) once a day. The dose may later be increased to 100 mg losartan potassium (two Losartan Mylan 50 mg Film-Coated Tablets) once daily depending on your blood pressure response.

Losartan Mylan tablets may be administered with other blood pressure lowering medicines (e.g. diuretics, calcium channel blockers, alpha- or beta-blockers, and centrally acting agents) as well as with insulin and other commonly used medicines that decrease the level of glucose in the blood (e.g. sulfonylureas, glitazones and glucosidase inhibitors).

#### Adult patients with Heart Failure

Treatment usually starts with 12.5 mg losartan potassium (one Losartan Mylan 12.5 mg Film-Coated Tablet) once a day.

Generally, the dose should be increased weekly step-by-step (i.e., 12.5 mg daily during the first week, 25 mg daily during the second week, 50 mg daily during the third week, 100 mg daily during the fourth week, 150 mg daily during the fifth week) up to the maintenance dose as determined by your physician. A maximum dose of 150 mg losartan potassium (for example, three tablets of Losartan Mylan 50 mg or one tablet each of Losartan Mylan 100 mg and Losartan Mylan 50 mg) once daily may be used.

For the doses not achievable with Losartan Mylan, other medicinal products containing losartan potassium in appropriate dose should be prescribed by your doctor.

In the treatment of heart failure, losartan potassium is usually combined with a diuretic (medicine that increases the amount of water that you pass out through your kidneys) and/or digitalis (medicine that helps to make the heart stronger and more efficient) and/or a beta-blocker.

#### **Dosage in special patient groups**

The doctor may advise a lower dose, especially when starting treatment in certain patients such as those treated with diuretics in high doses, in patients with liver impairment, or in patients over the age of 75 years. The use of losartan potassium is not recommended in patients with severe hepatic impairment (see section "Do not take Losartan Mylan").

#### **Administration**

The tablets should be swallowed whole with a glass of water. You should try to take your daily dose at about the same time each day. It is important that you continue to take Losartan Mylan until your doctor tells you otherwise.

The tablet can be divided into equal doses.

#### **If you take more Losartan Mylan than you should**

If you accidentally take too many tablets, or a child swallows some, contact your doctor immediately. Symptoms of overdose are low blood pressure, increased heartbeat, possibly decreased heartbeat.

#### **If you forget to take Losartan Mylan**

If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for a forgotten tablet. If you have any further questions on the use of this product, ask your doctor or pharmacist.

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

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

If you experience the following, stop taking Losartan Mylan tablets and tell your doctor immediately or go to the casualty department of your nearest hospital:

A severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing).

This is a serious but rare side effect, which affects more than 1 out of 10,000 patients but fewer than 1 out of 1,000 patients. You may need urgent medical attention or hospitalisation.

Muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown which can be life-threatening and lead to kidney problems (rhabdomyolysis)

This side effect is of a not known frequency (frequency cannot be estimated from the available data).

The side effects of medicines are classified as follows:

**very common:** affects more than 1 user in 10

**common:** affects 1 to 10 users in 100

**uncommon:** affects 1 to 10 users in 1000

**rare:** affects 1 to 10 users in 10000

**very rare:** affects less than 1 users in 10000 patients

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

The following side effects have been reported with Losartan Mylan:

*Common:*

- dizziness
- spinning sensation (vertigo)
- low blood pressure (especially after excessive loss of water from the body within blood vessels e.g. in patients with severe heart failure or under treatment with high dose diuretics)
- dose-related orthostatic effects such as lowering of blood pressure appearing when rising from a lying or sitting position resulting in a dizzy spell
- debility
- fatigue
- too little sugar in the blood (hypoglycaemia)
- too much potassium in the blood (hyperkalaemia)
- changes in kidney function including kidney failure

- a condition in which the amount of oxygen-carrying pigment (haemoglobin) in the blood is below normal, with the following symptoms; tiredness, headaches, being short of breath when exercising, dizziness and looking pale (anaemia)
- increase in blood urea, serum creatinine and serum potassium in patients with heart failure

*Uncommon:*

- feeling drowsy (somnolence)
- headache
- sleep disorders
- feeling of increased heart rate (palpitations)
- a pain or uncomfortable feeling in the chest, often spreading to the arms or neck and sometimes to the shoulders and back. This may be caused by too little blood and oxygen getting to the heart (angina pectoris)
- shortness of breath (dyspnoea)
- stomach pain
- severe constipation (obstipation)
- diarrhoea
- feeling sick (nausea)
- being sick (vomiting)
- hives (urticaria)
- itching (pruritus)
- rash
- accumulation of fluid resulting in localised swelling (oedema)
- cough

*Rare:*

- narrowage or blockage of blood vessels (vasculitis including Henoch-Schonlein purpura)
- numbness or tingling sensation (paraesthesia)
- fainting (syncope)
- very rapid and irregular heartbeat (atrial fibrillation)
- damage to part of the brain caused by an interruption to its blood supply (stroke)
- with the following symptoms; nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine (hepatitis)
- elevated levels of liver enzyme (blood alanine aminotransferase (ALT)), usually resolved upon discontinuation of treatment.

*Not known:*

- low blood platelet count which can lead to bleeding or bruising more easily than normal (thrombocytopenia)
- migraine
- liver function abnormalities
- muscle and joint pain
- flu-like symptoms
- back pain
- urinary tract infection
- increased sensitivity to the sun (photosensitivity)
- impotence
- inability to develop or maintain an [erection](#) of the [penis](#) (erectile dysfunction)
- inflammation of the pancreas with the following symptoms; severe upper stomach pain, often with nausea and vomiting (pancreatitis)
- low levels of sodium in the blood (hyponatraemia)
- depression
- generally feeling unwell (malaise)
- ringing, buzzing, roaring, or clicking in the ears (tinnitus)
- taste disturbance or loss of taste

Side effects in children are similar to those seen in adults.

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

## **5. HOW TO STORE LOSARTAN MYLAN:**

Keep out of the reach and sight of children.

Do not use Losartan Mylan after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Losartan Mylan does not require any special storage conditions. Do not open the blister pack until you are ready to take the 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 Losartan Mylan Film-Coated Tablets contains**

The active substance is losartan potassium.

Each Losartan Mylan 12.5 mg tablet contains 12.5 mg of losartan potassium.

Each Losartan Mylan 50 mg tablet contains 50 mg of losartan potassium.

Each Losartan Mylan 100 mg tablet contains 100 mg of losartan potassium.

The other ingredients are lactose monohydrate, microcrystalline cellulose (PH102), pregelatinized maize starch, magnesium stearate, hydroxypropyl cellulose (E463), hypromellose (E464), titanium dioxide (E171).

### **What Losartan Mylan Film-Coated Tablets looks like and contents of the pack**

Losartan Mylan 12.5 mg tablet is supplied as a white, round, biconvex, film coated tablets debossed with “L” on one side and ‘M’ on the other side.

Losartan Mylan 50 mg tablet is supplied as a white, oval shaped, biconvex, beveled edge, film coated tablet debossed with “LN” and “50” on either side of score line on one side of the tablet and ‘M’ on the other side. The tablet can be divided into equal doses.

Losartan Mylan 100 mg tablet is supplied as a white, tear drop shaped, biconvex, film coated tablets debossed with “LN100” on one side and ‘M’ on the other side.

The blister pack comprises of white opaque PVC film on one side and aluminum foil coated with heat seal lacquer on the other side.

The white opaque HDPE bottle comprises of a round wide mouth HDPE heat seal lined bottle with white opaque polypropylene cap.

Losartan Mylan tablets are supplied in blisters containing 7, 10, 14, 21, 28, 30, 38, 56, 60, 84, 90, 98, 99 and 100 tablets and bottles containing 500, 1000 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

### **Manufacturers**

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Generics [UK] Ltd., Station Close, Potters Bar, Hertfordshire EN6 1TL, United Kingdom

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

### **This medicinal product is authorized in the Member States of the EEA under the following Names:**

Austria	Arcalos 50 mg & 100 mg Filmtabletten
Belgium	Losartan Mylan Pharma
Cyprus	Losartan Mylan
Czech Republic	Losartan Mylan 12.5 mg, 25 mg, 50 mg & 100 mg potahované tablety
Denmark	Solartan
Finland	Solartan
France	LOSARTAN MYLAN PHARMA 12.5 mg, 50 mg & 100 mg comprimé pelliculé
Germany	Losartan Mylan 12.5 mg, 50 mg & 100 mg Filmtabletten
Hungary	Losartan Mylan 25 mg, 50 mg & 100 mg Filmtableta
Ireland	Losartan Mylan 12.5 mg , 50 mg & 100 mg Film-coated Tablets
Italy	Losartan Mylan
Luxembourg	Losartan Mylan Pharma
Norway	Losartan Mylan 12,5 mg, 25 mg, 50 mg, 100 mg tablet, filmdrasjert
Netherlands	Losartankalium Mylan 12.5 mg, 25 mg, 50 mg & 100 mg, filmomhulde tabletten
Poland	Tenlosar
Portugal	Tenlosarian
Romania	Losartan Mylan 12.5 mg, 25 mg, 50 mg & 100 mg comprimate filmate
Slovenia	Losartan Generics 50 mg & 100 mg filmsko obložene tablete
Spain	Losartan MYLAN Pharmaceuticals 12,5 mg inicio comprimidos EFG Losartan MYLAN Pharmaceuticals 25 mg, 50 mg, 100 mg comprimidos EFG
Sweden	Solartan
United Kingdom	Losartan Potassium 25 mg, 50 mg & 100 mg Film-coated Tablets

**This leaflet was last approved in 02/2015**