PACKAGE LEAFLET: INFORMATION FOR THE USER

Myzaar 12.5 mg Film Coated Tablets
Myzaar 50 mg Film Coated Tablets
Myzaar 100 mg Film Coated Tablets

(Losartan potassium)

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 of the side effects, talk to your doctor of pharmacist. This includes any possible side effects not listed in the leaflet.

What is in this leaflet:

The name of your medicine is Myzaar 12.5mg, 50 mg or 100 mg Film Coated Tablets (referred to as Myzaar Tablets in this leaflet).

1. What Myzaar Tablets are and what they are used for

Losartan 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 prevents the binding of angiotensin-II to those receptors, causing blood vessels to relax which in turn lowers the blood pressure. Losartan slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Myzaar Tablets are used:
- to treat patients with high blood pressure (hypertension)
- to protect the kidney in hypertensive type 2 diabetic patients with laboratory evidence of impaired renal function and proteinuria ≥ 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, medicines 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.

- in patients with high blood pressure and a thickening of the left ventricle, Myzaar Tablets have been shown to decrease the risk of stroke ("LIFE indication").

2. What you need to know before you take Myzaar Tablets

Do not take Myzaar Tablets

- if you are allergic to losartan or any of the other ingredients of this medicine (listed in section 6).
- if your liver function is severely impaired.
- if you are more than 3 months pregnant. (It is also better to avoid Myzaar Tablets in early pregnancy -see pregnancy section)

Warnings and precautions

Talk to your doctor or pharmacist before taking Myzaar Tablets:

- if you have a history of angiooedema (swelling of the face, lip, throat, and/or tongue) (see also section 4 'Possible side effects').
- you suffer from excessive vomiting or diarrhoea leading to an extreme loss of fluid and/or salt from your body
- if you receive diuretics (medicines that increase the amount of water that you can pass out through your kidneys) or are under dietary salt restrictions leading to an extreme loss of fluid and salt in you 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 section 2 "Do not take Myzaar" and 3 'Dosage in special patients groups'
- if you suffer from heart failure with or without renal impairment or concomitant severe life threatening cardiac arrhythmias.
- 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 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).
- You must tell your doctor if you think you are (or might become) pregnant. Myzaar Tablets are 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

Myzaar Tablets have been studied in children. For more information, talk to your doctor. Myzaar Tablets are not recommended for use in children suffering from kidney or liver problems, or children under 6 years old, as limited data are available in these patient groups.

Other medicines and Myzaar Tablets
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 the treatment with Myzaar Tablets:

- 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, baclofene, amifostine

- medicines which retain potassium or may increase potassium levels (e.g. potassium supplements or potassium-containing salt substitutes or potassium-sparing medicines such as certain diuretics [amiloride, trimteren, 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 lowering effect of losartan.

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 without close supervision by your doctor. Special precautionary measures (e.g. blood tests) may be appropriate.

Myzaar Tablets with food and drink

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

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. Myzaar Tablets is unlikely to affect your ability to drive or use machines. However, as with many other medicines used to treat high blood pressure, losartan may cause dizziness or drowsiness in some people. If you experience dizziness or drowsiness, you should consult your doctor before attempting such activities.

Myzaar Tablets contain lactose
Myzaar 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 Myzaar Tablets

Always take Myzaar Tablets exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will decide on the appropriate dose of Myzaar Tablets, depending on your condition and whether you are taking other medicines. It is important to continue taking Myzaar Tablets 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 (one tablet Myzaar 50 mg) 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 (two tablets Myzaar 50 mg) once daily.
If you have the impression that the effect of losartan is too strong or too weak, please talk to your doctor or pharmacist.

Use in children and 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 per kg of body weight administered once a day (up to 25 mg of losartan). The doctor may increase the dose if blood pressure is not controlled.
Other form(s) of this medicine may be more suitable for children; ask your doctor or pharmacist.

Adult patients with high blood pressure and Type 2 diabetes
Treatment usually starts with 50 mg losartan (one tablet Myzaar 50 mg) once a day. The dose may later be increased to 100 mg losartan (two tablets Myzaar 50 mg) once daily depending on your blood pressure response.
Myzaar 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 (one tablet Myzaar 12.5 mg) 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) up to the usual maintenance dose of 50 mg losartan (one tablet Myzaar 50 mg) once daily, according to your condition.
In the treatment of heart failure, losartan 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 is not recommended in patients with severe hepatic impairment (see section "Do not take losartan").

Administration
The tablets should be swallowed 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 Myzaar Tablets until your doctor tells you otherwise.

If you take more Myzaar tablets 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 Myzaar Tablets
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, Myzaar Tablets can cause side effects, although not everybody gets them.

If you experience the following, stop taking Myzaar 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.

The following side effects have been reported with Myzaar Tablets:
Common (may affect up to 1 in 10 people):
- dizziness,
- low blood pressure,
- feeling or being weak,
- fatigue,
- reduced number of red blood cells (anaemia)
- too less sugar in the blood (hypoglycaemia,)
- too much potassium in the blood (hyperkalaemia)

- increase in blood urea,
- increase in serum creatinine and serum potassium in patients
- changes in kidney function (may be reversible upon discontinuation of treatment) including kidney failure,

Uncommon (may affect up to 1 in 100 people):
- somnolence,
- headache,
- sleep disorders,
- feeling of increased heart rate (palpitations),
- severe chest pain (angina pectoris),
- 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),
- shortness of breath (dyspnoea),
- cough
- abdominal pain,
- severe constipation (obstipation),
- diarrhoea,
- nausea,
- vomiting,
- hives (urticaria),
- itching (pruritus),
- rash,
- localised swelling (oedema).

Rare (may affect up to 1 in 1,000 people):
- inflammation of blood vessels (vasculitis including Henoch-Schonlein purpura),
- numbness or tingling sensation (paraesthesia),
- fainting (syncope),
- very rapid and irregular heartbeat (artrial fibrillation) brain attack (stroke),
- inflammation of the liver (hepatitis),
- elevated blood alanine aminotransferase (ALT) levels, usually resolved upon discontinuation of treatment.

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

- reduced number of thrombocytes,
- dose-related orthostatic effects such as lowering of blood pressure appearing when rising from a lying or sitting position,
- ringing sound in ear (tinnitus)
- liver function abnormalities,
- increased sensitivity to the sun (photosensitivity),
- migraine
- change in taste
- erectile dysfunction, impotence
- depression

- inflammation of the pancreas (pancreatitis),
- muscle and joint pain
- low blood sodium levels (hyponataemia)
- flu-like symptoms
- back pain and urinary track infection.

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

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. How to store Myzaar Tablets

Keep out of the sight and reach of children.

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

Store Myzaar Tablets in the original pack.
Do not open the blister until you are ready to take the medicine.

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 to protect the environment.

6. Contents of the pack and other information

What Myzaar Tablets contain

The active substance is losartan potassium

Each tablet contains 12.5mg, 50 mg & 100 mg of Losartan potassium, equivalent to 11.44mg, 45.76 mg & 91.52 mg of losartan.

The other ingredients are lactose monohydrate, pre-gelatinised starch, microcrystalline cellulose, magnesium stearate. The coating includes hydroxypropylcellulose, hypromellose, titanium dioxide E171 and Brilliant Blue FCF Aluminium Lake E 133 (in 12.5 mg tablets only).

What Myzaar Tablets look like and contents of the pack
The film-coated tablets are round.
The 12.5 mg tablets are blue
The 50 mg and 100 mg tablets are white.

Myzaar is available in blister packs of 10, 14, 20, 21, 28, 28 (cal), 30, 50x1, 56, 60, 98, 98 (cal), 100, 210 and 280* tablets.
*Not all pack sizes may be marketed

HDPE bottle packs: HDPE bottles with silica gel desiccant containing 100 and 250 film-coated tablets

Marketing Authorisation Holder and Manufacturer:
McDermott Laboratories Ltd.
t/a Gerard Laboratories,
35/36 Baldoyle Industrial Estate,
Grange Road,
Dublin 13,
Ireland.

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

Member State	**Invented name**
Germany	Losartan-dura 12.5mg, 25mg, 50mg & 100mg Filmtabletten
Austria	Losartan Arcana 12,5 mg & 50mg - Filmtabletten
Finland	Losartan Mylan 25mg, 50mg & 100mg tabletti, kalvopaallysteinen
Ireland	Myzaar 12.5mg, 50mg & 100mg Film-coated tablets
Poland	Losagen 12.5mg, 25mg, 50mg & 100mg
Portugal	Losartan Mylan 50mg & 100mg comprimidos revestidos por película
Slovenia	Losartan Mylan 50mg & 100mg filmsko oblozene tablete

This leaflet was last approved in February 2013.