Package Leaflet: Information for the patient

# 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 or pharmacist. This includes any possible side effects not listed in the leaflet. See section 4.

**What is in this leaflet**


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


## 1. What Myzaar is and what it is used for

Myzaar contains the active substance losartan, which 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 are 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 ≥ 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, losartan has been shown to decrease the risk of stroke ("LIFE indication").

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

**Do not take Myzaar**
- if you are allergic to losartan or any of the other ingredients of this medicine (listed in section 6).
- if you are more than 3 months pregnant. (It is also better to avoid losartan in early pregnancy - see pregnancy section).
- if your liver function is severely impaired.
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

**Warnings and precautions**
Talk to your doctor or pharmacist before taking Myzaar. You must tell your doctor if you think you are (or might become) pregnant. Losartan 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 also important to tell your doctor before taking Myzaar:

- if you have a history of angioedema (swelling of the face, lip, 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 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 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 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. Special caution is necessary when you are treated with a β-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 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 Myzaar"

**Children and adolescents**
Myzaar has been studied in children. For more information, talk to your doctor.
Myzaar is not recommended for use in children suffering from kidney or liver problems, as limited data are available in these patient groups.

Myzaar is not recommended for use in children under 6 years old, as it has not been shown to work in this age group.

**Other medicines and Myzaar**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription or herbal medicines and natural products.

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

Take particular care if you are taking the following medicines while under the treatment with Myzaar:
- 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.
- an ACE-inhibitor or aliskiren (see also information under the headings "Do not take Myzaar" and "Warnings and precautions").
- 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, triamterene, spironolactone] or heparin).
- non-steroidal anti-inflammatory drugs such as indometacin, 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.
- fluconazole (antifungal) and rifampicin (antibiotic) may reduce the effects 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.

**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 before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Myzaar. Myzaar 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. Myzaar 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**
No studies on the effects on the ability to drive and use machines have been performed. Myzaar 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 contains lactose**
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

Always take this medicine 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, depending on your condition and whether you are taking other medicines.
It is important to continue taking Myzaar 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**
Children below 6 years of age
Myzaar is not recommended for use in children under 6 years old, as it has not been shown to work in this age group.

Children aged 6 - 18 years old
The recommended starting dose in patients who weigh between 20 and 50 kg is 25 mg once daily (up to a maximum of 50 mg of losartan once daily). The doctor may increase the dose if blood pressure is not controlled.


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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 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, 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 (for example three tablets of Myzaar 50 mg or one tablet each of Myzaar 100 mg and Myzaar 50 mg) once daily may be used.

In the treatment of heart failure, losartan is usually combined with a diuretic (a medicine that increases the amount of water that you pass out through your kidneys) and/or digitalis (a 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 Myzaar").

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 until your doctor tells you otherwise.
Myzaar may be taken with or without food.

**If you take more Myzaar 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**
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 dose.

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.

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

**Common (may affect up to 1 in 10 people)**
- build up of fluid in the body causing swelling in your legs, ankles or feet; you may pass little or no urine or have severe pain in the lower back. These may be signs of changes in kidney function, which can lead to kidney failure.

**Uncommon (may affect up to 1 in 100 people)**
- a feeling of tightness in the chest or severe chest pain (angina pectoris).

**Rare (may affect up to 1 in 1,000 people)**
- a severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing – which may include angioedema),
- very rapid and irregular heartbeat (atrial fibrillation)
- numbness or weakness of the face, legs or arms, visual disturbance, slurred or loss of speech. These may be signs of a lack of blood flow or blockage in the blood vessels of the brain (stroke),
- fever, feeling sick (nausea), being sick (vomiting), yellowing of the eyes and skin (jaundice); these may be signs of inflammation of the liver (hepatitis).

**Not known (frequency cannot be estimated from the available data):**
- severe pain in the abdomen with feeling or being sick; these may signs of inflammation of the pancreas (pancreatitis),
- unexplained muscle pain, dark (tea-coloured) urine; these may be signs of muscle problems (rhabdomyolysis).

The following side effects have also been reported:

**Common (may affect up to 1 in 10 people):**
- dizziness,
- 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,
- feeling or being weak,
- fatigue,
- reduced number of red blood cells (anaemia),
- low sugar (glucose) levels in the blood (hypoglycaemia),
- high potassium levels in the blood (hyperkalaemia),
- increase in blood urea,
- increase in serum creatinine and serum potassium.

**Uncommon (may affect up to 1 in 100 people):**
- somnolence,
- headache,
- sleep disorders,
- feeling of increased heart rate (palpitations),
- 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),
- 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,
- ringing, buzzing, roaring or clicking in the ears (tinnitus),
- liver function abnormalities,
- increased sensitivity to the sun (photosensitivity),
- migraine,
- change in taste,
- erectile dysfunction, impotence,
- depression,
- muscle and joint pain,
- low blood sodium levels (hyponatraemia), which can cause confusion, muscle twitching or abnormal heart rhythm,
- flu-like symptoms
- generally feeling unwell (malaise),
- back pain and urinary tract infection.

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

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. This includes any 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; E-mail:medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Myzaar

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

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

This medicine does not require any special storage conditions.
Do not open the blister pack 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 protect the environment.

## 6. Contents of the pack and other information

**What Myzaar contains**
The active substance is losartan.

Each film-coated tablet contains 50 mg or 100 mg of losartan potassium, equivalent to 45.76 mg or 91.52 mg of losartan.

The other ingredients are lactose monohydrate (see section 2 “Myzaar contains lactose”), pregelatinised maize starch, microcrystalline cellulose, magnesium stearate. The coating includes hydroxypropylcellulose, hypromellose, titanium dioxide (E171).

**What Myzaar looks like and contents of the pack**
The film-coated tablets are round.

The 50 mg and 100 mg tablets are white.

**HDPE bottle packs:** HDPE bottles with silica gel desiccant contained in the polypropylene lid containing 100 and 250 film-coated tablets. Do not eat the desiccant.

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* film-coated tablets.

*Not all pack sizes may be marketed

**Marketing Authorisation Holder**
McDermott Laboratories Ltd.
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**Manufacturer**
Laboratorios Liconsa, S.A., Avda. Miralcampo, No. 7, Polígono Industrial, Miralcampo, 19200 Azuqueca de Henares (Guadalajara), Spain.
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.

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

| Member State | Invented name |
|---|---|
| Germany | Losartan-dura 50mg & 100mg Filmtabletten |
| Ireland | Myzaar 50mg & 100mg Film-coated tablets |
| Poland | Losagen |
| Portugal | Losartan Mylan |

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