

Package leaflet: Information for the patient

Myzaar Comp 50 mg/12.5 mg Film-coated Tablets Myzaar Comp 100 mg/25 mg Film-coated Tablets losartan potassium and hydrochlorothiazide

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

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

Myzaar Comp is a combination of an angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide). 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 these receptors, causing the blood vessels to relax which in turn lowers the blood pressure. Hydrochlorothiazide works by making the kidneys pass more water and salt. This also helps to reduce blood pressure.

Myzaar Comp is indicated for the treatment of essential hypertension (high blood pressure)

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

Do not take Myzaar Comp

- if you are allergic to losartan potassium, to hydrochlorothiazide or to any of the other ingredients in this medicine (listed in section 6)
- if you are allergic to other sulfonamide-derived substances (e. g. other thiazides, some antibacterial drugs such as co-trimoxazole; ask your doctor if you are not sure)
- if you are more than 3 months pregnant. (It is also better to avoid Myzaar Comp in early pregnancy - See pregnancy section)
- if you have severely impaired liver function
- if you have a blockage, or reduced flow of bile, such as cholestasis (can be due to impaired liver function or gallstones) causing jaundice, dark urine, pale stools and itching over the skin
- if you have severely impaired kidney function or your kidneys are not producing any urine.
- if you have low potassium, low sodium or high calcium levels which can not be corrected by treatment
- if you are suffering from gout
- if you have diabetes or impaired kidney function and are taking a medicine called aliskiren to reduce blood pressure.

Warnings and precautions

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

- if you have previously suffered from swelling of the face, lips throat or tongue
- if you take diuretics (water tablets)
- if you are on a salt-restricted diet
- if you have or have had severe vomiting and/or diarrhoea or are dehydrated
- if you have heart failure
- if you have cerebrovascular disease (disease of the blood vessels supplying the brain)
- if your liver function is impaired (see section 2 “Do not take Myzaar Comp”)
- if you have narrow arteries to your kidneys (renal artery stenosis) or only have one functioning kidney, or you have recently had a kidney transplant
- if you have narrowing of the arteries (atherosclerosis), angina pectoris (chest pain due to poor heart function)
- if you have ‘aortic or mitral valve stenosis’ (narrowing of the valves of the heart) or ‘hypertrophic cardiomyopathy’ (a disease causing thickening of heart muscle)
- if you are diabetic
- if you have had gout
- if you have or have had an allergic condition, asthma or a condition that causes joint pain, skin rashes and fever (systemic lupus erythematosus)
- if you have high calcium or low potassium levels or you are on a low potassium diet
- if you have high fat levels in your blood (cholesterol and triglycerides), as the hydrochlorothiazide in this medicine may cause these to increase.
- if you need to have an anaesthetic (even at the dentist) or before surgery, or
- if you are going to have tests to check your parathyroid function, you must tell your doctor or medical staff that you are taking Myzaar Comp tablets.
- 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 of African or Caribbean descent. This medicine may not be as effective for you.
- if you are taking a medicine called aliskiren to reduce blood pressure.

Other medicines and Myzaar Comp

Tell your doctor or pharmacist if you are taking , have recently taken or might take any other medicines, including medicines obtained without a prescription.

Diuretic agents such as the hydrochlorothiazide contained in Myzaar Comp may interact with other medicines.

You should avoid taking Myzaar Comp with:

- lithium (used to treat depression),
- potassium supplements, potassiumsparing diuretics (spironolactone, triamterene, amiloride) and potassium salts.

It is also important for your doctor to know if you are taking any of the following medicines:

- other medicines to reduce your blood pressure such as ACE-inhibitors (e.g. ramipril), methyl dopa,

- other diuretics (“water tablets”),
- medicines for the treatment of gout (e.g. probenecid, sulfinpyrazone and allopurinol),
- medicines to control heart rhythm (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide)
- steroids or ACTH (also called corticotropin, a synthetic hormone used to check the function of your adrenal gland)
- medicines to treat cancer (e.g. amifostine, cyclophosphamide, methotrexate),
- pain killers such as non-steroidal anti-inflammatory drugs (e.g. ibuprofen) or high dose salicylates (e.g. aspirin),
- drugs for treatment of fungal infections (e.g. fluconazole, amphotericin B by injection),
- arthritis medicines,
- resins used for high cholesterol, such as cholestyramine, colestipol,
- medicines which relax your muscles (e.g. tubocurarine, baclofen),
- sleeping tablets,
- opioid medicines such as morphine,
- ‘pressor amines’ such as adrenaline or other drugs from the same group,
- oral agents for diabetes (e.g. metformin) or insulins,
- medicines to treat neurological disorders such as depression, anxiety, and schizophrenia including tricyclic antidepressants and neuroleptics (such as chlorpromazine, cyamemazine, levomepromazine, thioridazine, trifluoperazine, pimozide, amisulpride, sulpiride, sultopride, tiapride, haloperidol, droperidol),
- medicines which may give you a dry mouth or blurred vision (e.g. atropine, biperiden)
- medicines for mouth ulcers (e.g. choline salicylate),
- immunosuppressants used for the treatment of auto-immune disorders or following transplant surgery to prevent rejection (e.g. ciclosporin), some laxatives (e.g. senna, bisacodyl)
- digoxin or other cardiac glycosides (for the treatment of heart problems),
- bepridil (used to treat angina pectoris),
- cisapride or diphermanil (used to treat gastrointestinal disorders),
- erythromycin by injection (an antibiotic),
- rifampicin (used to treat tuberculosis),
- halofantrine (used to treat certain types of malaria),
- terfenadine or mizolastine (antihistamines for hay fever or allergies),
- pentamidine (used to treat pneumonia),
- vincamine by injection (used to treat memory loss in the elderly),
- calcium including calcium supplements,
- carbamazepine (an antiepileptic).
- glycyrrhizin (found in liquorice and often used in cough medicines if taken in large amounts)
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Also inform your doctor you are taking Myzaar Comp if you will be undergoing a radiographic procedure and will be given iodine contrast media.

Special precautionary measures (e.g. blood tests) may also be appropriate.

Taking Myzaar Comp with food and drink

You are advised not to drink alcohol whilst taking these tablets: alcohol and Myzaar Comp may increase each other’s effects.

Dietary salt in excessive quantities may counteract the effect of Myzaar Comp. Large amounts of glycyrrhizin which is contained in liquorice can affect how well Myzaar Comp works.

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 Comp before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Myzaar Comp. Myzaar Comp 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 Comp is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breastfeed, especially if your baby is a newborn, or born prematurely.

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

Driving and using machines

When you begin treatment with this medication, you should not perform tasks which may require special attention (for example, driving an automobile or operating dangerous machinery) until you know how you tolerate your medicine. You may feel dizzy or drowsy, especially at the beginning of your treatment or when the dose is increased.

Myzaar Comp contains lactose

If you have been told by your doctor that you are lactose intolerant or have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Myzaar Comp

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

Your doctor will decide on the appropriate dose of Myzaar Comp depending on your condition and whether you are taking other medicines. It is important to continue taking Myzaar Comp for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

The recommended dose of Myzaar Comp for most patients with high blood pressure is 1 tablet of Myzaar Comp 50 mg/12.5 mg per day to control blood pressure over the 24-hour period. This can be increased to 2 tablets once daily of Myzaar Comp 50 mg/12.5 mg Film-coated Tablets or changed to 1 tablet daily of Myzaar Comp 100 mg/25 mg Film-coated Tablets (a stronger strength) per day. The maximum daily dose is 2 tablets per day of Myzaar Comp 50 mg/12.5 mg Film-coated Tablets or 1 tablet daily of Myzaar Comp 100 mg/25 mg Film-coated Tablets.

Use in elderly patients

Myzaar Comp works equally well in and is equally well tolerated by most older and younger adult patients. Most older patients require the same dose as younger patients.

Use in children and adolescents

There is no experience with the use of Myzaar Comp in children. Therefore, Myzaar Comp should not be given to children.

Taking your medicine

Myzaar Comp tablets should be swallowed with a glass of water and can be taken with or without food.

If you take more Myzaar Comp than you should

In case of an overdose, contact your doctor immediately so that medical attention may be given promptly. Overdose can cause a drop in blood pressure, fast heart rate, slow pulse, changes in blood composition, and dehydration.

If you forget to take Myzaar Comp

Try to take Myzaar Comp daily as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule.

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 Comp tablets and tell your doctor immediately or go to the casualty department of your nearest hospital:

Common (may affect up to 1 in 10 people):

- Kidney problems including inflammation of the kidneys and kidney failure,

Uncommon (may affect up to 1 in 100 people):

- Angina (chest pain), abnormal heartbeat (fast, slow or irregular), cerebrovascular accident (TIA, “mini-stroke”), heart attack,
- Blood problems including:
 - Reduction in white blood cells leading to an increase in infections,
 - Anaemia, red or brownish spots on the skin (sometimes especially on the feet, legs, arms and buttocks, with joint pain, swelling of the hands and feet and stomach pain), clotting problems and bruising,
- Jaundice (yellowing of the eyes and skin), inflammation of the pancreas,
- Pneumonia, water on the lungs (which causes difficulty breathing),
 - If you develop a severe skin rash that causes blistering that can affect the mouth, throat, nose, genitals.

This is often accompanied by flu-like symptoms (Toxic Epidermal Necrolysis (TEN)).

Rare (may affect up to 1 in 1,000 people):

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

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

- Unexplained muscle pain with dark (tea-coloured) urine (rhabdomyolysis).

The following other side effects have been reported:

Common (may affect up to 1 in 10 people):

- Cough, upper airway infection, congestion in the nose, sinusitis, sinus disorder,
- Diarrhoea, abdominal pain, nausea, indigestion,

- Muscle pain or cramps, leg pain, back pain,
- Insomnia, headache and/or neck pain, dizziness,
- Weakness, tiredness, chest pain,
- Increased potassium levels (which can cause an abnormal heart rhythm), decreased haemoglobin levels,
- Decreased sugar in the blood.

Uncommon (may affect up to 1 in 100 people):

- Loss of appetite, increased uric acid levels or frank gout, increased blood sugar levels, low levels of blood sodium and potassium, increase in urea and creatinine levels in the blood,
- Anxiety, nervousness, panic disorder (recurring panic attacks), confusion, depression, abnormal dreams, sleep disorders, sleepiness, memory impairment,
- Pins and needles or similar sensations, pain in the extremities, trembling, migraine, fainting,
- Blurred vision, burning or stinging in the eyes, conjunctivitis, worsening eyesight, seeing things in yellow,
- Ringing, buzzing, roaring or clicking in the ears, vertigo,
- Low blood pressure, which may be associated with changes in posture (feeling light-headed or weak when you stand up), palpitations,
- Inflammation of blood vessels, which is often associated with a skin rash or bruising,
- Sore throat, breathlessness, bronchitis, nosebleed, runny nose, congestion,
- Constipation, wind, stomach upsets, stomach spasms, vomiting, dry mouth, inflammation of a salivary gland, toothache,
Hives, itching, inflammation of the skin, rash, redness of the skin, sensitivity to light, dry skin, flushing, sweating, hair loss,
- Pain in the arms, shoulders, hips, knees or other joints, joint swelling, stiffness, muscle weakness, widespread pain with a heightened and painful response to pressure
- Frequent urination including at night, urinary infection, sugar in the urine,
- Decreased sexual appetite, impotence,
- Swelling of the face, localised swelling, fever.

Rare (may affect up to 1 in 1,000 people):

- Abnormal liver function tests

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

- Flu-like symptoms,
- Generally feeling unwell.

Reporting of side effects

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

You can also report side effects directly via

IMB Pharmacovigilance,
Earlsfort Terrace,
IRL- Dublin 2;

Tel: +353 1 6764971;

Fax: +353 1 6762517.

Website: www.imb.ie;

e-mail: imbpharmacovigilance@imb.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Myzaar Comp

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 label or carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

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 Comp contains

The active substances are: losartan potassium and hydrochlorothiazide.

Myzaar Comp 50 mg/12.5 mg Film-coated Tablet: contains 50 mg of losartan potassium and 12.5 mg of hydrochlorothiazide.

Myzaar Comp 100 mg/25 mg Film-coated Tablet: contains 100 mg losartan potassium and 25 mg of hydrochlorothiazide.

- The other ingredients are microcrystalline cellulose, lactose monohydrate (see section 2 “Hydrochlorothiazide contains lactose”), pregelatinised maize starch, magnesium stearate, hydroxypropylcellulose, hypromellose, titanium dioxide (E171) and yellow iron oxide (E172).

What Myzaar Comp looks like and contents of the pack

Myzaar Comp 50 mg/12.5 mg Film-coated Tablets are round, yellow film-coated tablets.

Myzaar Comp 100 mg/25 mg Film-coated Tablets are round, yellow film-coated tablets.

Myzaar Comp 50 mg/12.5 mg Film-coated Tablets are available in blisters containing 10, 14, 20, 28, 30, 50, 56, 60, 98, 100 tablets and calendar packs containing 28 & 98 tablets.

Myzaar Comp 100 mg/25 mg Film-coated Tablets are available in blisters containing 10, 14, 20, 28, 30, 50, 56, 60, 98, 100 tablets and calendar packs containing 28 & 98 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
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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.

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

Austria “Losartan/HCT Arcana 50 mg/12,5 mg - Filmtabletten”, “Losartan/HCT Arcana 100 mg/25 mg - Filmtabletten”

Belgium “Co-Losartan Mylan 50mg/12,5mg filmomhulde tabletten”, “Co-Losartan Mylan 100mg/25mg filmomhulde tabletten”
Czech Republic “Losagen Combi 50mg / 12,5mg, potahované tablety”
Germany “Losartan-dura plus 50 mg/12,5 mg Filmtabletten”, “Losartan-dura plus 100 mg/25 mg Filmtabletten”
Hungary “Losartan - HCT - Generics [UK]”
Ireland “Myzaar Comp 50mg/12.5mg Film-Coated Tablets”, Myzaar Comp 100mg/25mg Film-Coated Tablets”
Italy “LosartanIdroclorotiazide Mylan Generics FCT”
Poland “Losagen Combi”
Portugal “Losartan + Hidroclortiazida Mylan”
Slovenia “Losartan HCT Mylan 50mg/12.5mg filmsko obložene tablete”, “Losartan HCT Mylan 100mg/25mg filmsko obložene tablete”
The Netherlands “Losartankalium/Hydrochloorthiazide Mylan 50/12,5 mg filmomhulde tabletten”, “Losartankalium/Hydrochloorthiazide Mylan 100/25mg filmomhulde tabletten”
UK “Losartan Potassium/Hydrochlorothiazide 50mg/12.5mg & 100mg/25mg Film-Coated Tablets”
“Losartan Potassium/Hydrochlorothiazide 100 mg /25 mg Film-Coated Tablets”

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