

Package leaflet: Information for the patient

Losartan/Hydrochlorothiazide Mylan 50 mg/12.5 mg Film-coated Tablets
Losartan/Hydrochlorothiazide Mylan 100 mg/12.5 mg Film-coated Tablets
Losartan/Hydrochlorothiazide Mylan 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, 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 Losartan/Hydrochlorothiazide Mylan is and what it is used for
2. What you need to know before you take Losartan/Hydrochlorothiazide Mylan
3. How to take Losartan/Hydrochlorothiazide Mylan
4. Possible side effects
5. How to store Losartan/Hydrochlorothiazide Mylan
6. Contents of the pack and other information

1. What Losartan/Hydrochlorothiazide Mylan is and what it is used for

Losartan/Hydrochlorothiazide Mylan 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.

Losartan/Hydrochlorothiazide Mylan is indicated for the treatment of essential hypertension (high blood pressure).

2. What you need to know before you take Losartan/Hydrochlorothiazide Mylan

Do not take Losartan/Hydrochlorothiazide Mylan

- if you are allergic to losartan, hydrochlorothiazide or to any of the other ingredients of 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 have severely impaired liver function
- if you have low potassium, low sodium or high calcium levels which cannot be corrected by treatment
- if you are suffering from gout
- if you are more than 3 months pregnant. (It is also better to avoid Losartan/Hydrochlorothiazide Mylan in early pregnancy – see Pregnancy section)
- if you have severely impaired kidney function or your kidneys are not producing any urine
- 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 Losartan/Hydrochlorothiazide Mylan.

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

Losartan/Hydrochlorothiazide 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/Hydrochlorothiazide Mylan

- if you have previously suffered from swelling of the face, lips, throat or tongue
- if you take diuretics (water pills)
- if you are on a salt-restricted diet
- if you have or have had severe vomiting and/or diarrhoea
- if you have heart failure
- if your liver function is impaired (see section 2 “Do not take Losartan/Hydrochlorothiazide Mylan”)
- 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 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 the doctor or medical staff that you are taking losartan potassium and hydrochlorothiazide 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 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/Hydrochlorothiazide Mylan”

Children and adolescents

There is no experience with the use of Losartan/Hydrochlorothiazide Mylan in children. Therefore, Losartan/Hydrochlorothiazide Mylan should **not** be given to children.

Other medicines and Losartan/Hydrochlorothiazide Mylan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Diuretic agents such as the hydrochlorothiazide contained in Losartan/Hydrochlorothiazide Mylan may interact with other medicines.

Preparations containing lithium should **not** be taken with Losartan/Hydrochlorothiazide Mylan without close supervision by your doctor.

Special precautionary measures (e.g. blood tests) may be appropriate if you take potassium supplements, potassium-containing salt substitutes or potassium-sparing medicines, other diuretics (“water tablets”), some laxatives, glycyrrhizin (found in liquorice), medicines for the treatment of gout, medicines to control heart rhythm or for diabetes (oral agents or insulins).

It is also important for your doctor to know if you are taking:

- other medicines to reduce your blood pressure
- steroids
- medicines to treat cancer
- pain killers
- drugs for treatment of fungal infections
- arthritis medicines
- resins used for high cholesterol, such as cholestyramine
- medicines which relax your muscles
- sleeping tablets
- opioid medicines such as morphine
- ‘pressor amines’ such as adrenaline or other drugs from the same group;
- oral agents for diabetes or insulins.

Please also inform your doctor if you are taking Losartan/Hydrochlorothiazide Mylan and you will be undergoing a radiographic procedure and will be given iodine contrast media.

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/Hydrochlorothiazide Mylan” and “Warnings and precautions”).

Losartan/Hydrochlorothiazide Mylan with food, drink and alcohol

You are advised not to drink alcohol whilst taking these tablets: alcohol and Losartan/Hydrochlorothiazide Mylan tablets may increase each other’s effects.

Dietary salt in excessive quantities may counteract the effect of Losartan/Hydrochlorothiazide Mylan tablets.

Losartan/Hydrochlorothiazide Mylan 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 Losartan/Hydrochlorothiazide 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/Hydrochlorothiazide Mylan. Losartan/Hydrochlorothiazide Mylan is not recommended during 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. Losartan/Hydrochlorothiazide 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.

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

Use in older people

Losartan/Hydrochlorothiazide Mylan 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.

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.

Losartan/Hydrochlorothiazide Mylan contains lactose

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

3. How to take Losartan/Hydrochlorothiazide Mylan

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 Losartan/Hydrochlorothiazide Mylan depending on your condition and whether you are taking other medicines. It is important to continue taking Losartan/Hydrochlorothiazide Mylan for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

High Blood Pressure

The recommended dose of Losartan/Hydrochlorothiazide Mylan for most patients with high blood pressure is 1 tablet of Losartan/Hydrochlorothiazide Mylan 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 Losartan/Hydrochlorothiazide Mylan 50 mg/12.5 mg film-coated tablets or changed to 1 tablet daily of Losartan/Hydrochlorothiazide Mylan 100 mg/25 mg film-coated tablets (a stronger strength) per day. The maximum daily dose is 2 tablets per day of Losartan/Hydrochlorothiazide Mylan 50 mg/12.5 mg film-coated tablets or 1 tablet daily of Losartan/Hydrochlorothiazide Mylan 100 mg/25 mg film-coated tablets.

If you take more Losartan/Hydrochlorothiazide Mylan 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, palpitations, slow pulse, changes in blood composition, and dehydration.

If you forget to take Losartan/Hydrochlorothiazide Mylan

Try to take Losartan/Hydrochlorothiazide Mylan 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 any of the following serious side effects, stop taking Losartan/Hydrochlorothiazide Mylan tablets and tell your doctor immediately or go to the casualty department of your nearest hospital:

- A severe rare (may affect up to 1 in 1,000 people) allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing) (anaphylactic reaction).
- A severe uncommon (may affect up to 1 in 100 people) skin reaction associated with painful red areas, large blisters, peeling of layers of skin. This is accompanied by fevers and chills, aching muscles and generally feeling unwell (toxic epidermal necrolysis).

The following 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
- Difficulty sleeping (insomnia), headache, dizziness
- Weakness, tiredness, chest pain
- Increased potassium levels (which can cause an abnormal heart rhythm), decreased haemoglobin levels
- Changes in kidney function including kidney failure
- Too low sugar in the blood (hypoglycaemia)

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

- 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), bruising, destruction of red blood cells (haemolysis), reduction in white blood cells, reduced number of platelets
- Loss of appetite, increased uric acid levels or frank gout, increased blood sugar levels, abnormal blood electrolyte levels
- Anxiety, nervousness, panic disorder (recurring panic attacks), confusion, depression, abnormal dreams, sleep disorders, sleepiness, memory impairment
- Pins and needles sensation, numbness or weakness of the arms and legs, tremor, 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, dizziness and spinning sensation (vertigo)
- Low blood pressure, which may be associated with changes in posture (feeling light-headed or weak when you stand up), angina (chest pain), abnormal heartbeat, cerebrovascular accident (TIA, “mini-stroke”), heart attack, palpitations, changes in the rhythm or rate of the heart beat (arrhythmias)
- Inflammation of blood vessels, which is often associated with a skin rash or bruising.
- Sore throat and discomfort when swallowing (pharyngitis), swelling and irritation of the voice box associated with loss of voice (laryngitis), breathlessness, bronchitis, swelling of the lungs (pneumonitis), water on the lungs (which causes difficulty breathing), nosebleed, runny nose, congestion
- Constipation, severe constipation (obstipation), wind, swelling and inflammation of the stomach lining (gastritis), stomach upsets, stomach spasms, vomiting, dry mouth, inflammation of a salivary gland, toothache
- Jaundice (yellowing of the eyes and skin), inflammation of the pancreas
- 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 or cramps
- Frequent urination including at night, abnormal kidney function including inflammation of the kidneys, urinary tract infection, sugar in the urine
- Decreased sexual appetite, impotence
- Swelling of the face, localised swelling (oedema), fever

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

- Inflammation of the liver (hepatitis), abnormal liver function tests

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

- Flu-like symptoms
- Unexplained muscle pain with dark (tea-colored) urine (rhabdomyolysis)
- Low levels of sodium in the blood (hyponatraemia)
- Generally feeling unwell (malaise)
- Disturbed taste (dysgeusia)

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 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 Losartan/Hydrochlorothiazide Mylan

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 carton, blister and bottle after EXP. The expiry date refers to the last day of that month.

Losartan/Hydrochlorothiazide Mylan does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Losartan/Hydrochlorothiazide Mylan film-coated tablets contains

The active substances are losartan potassium and hydrochlorothiazide

Losartan/Hydrochlorothiazide Mylan 50 mg/12.5 mg

Each tablet contains 50 mg of losartan potassium and 12.5 mg of hydrochlorothiazide.

Losartan/Hydrochlorothiazide Mylan 100 mg/12.5 mg

Each tablet contains 100 mg of losartan potassium and 12.5 mg of hydrochlorothiazide.

Losartan/Hydrochlorothiazide Mylan 100 mg/25 mg

Each tablet contains 100 mg of losartan potassium and 25 mg of hydrochlorothiazide.

Losartan/Hydrochlorothiazide Mylan 50 mg/12.5 mg and Losartan/Hydrochlorothiazide Mylan 100 mg/25 mg contain the following other ingredients: cellulose microcrystalline, lactose monohydrate, starch pregelatinized (maize), magnesium stearate, hydroxypropyl cellulose and titanium dioxide.

Losartan/Hydrochlorothiazide Mylan 50 mg/12.5 mg also contains: Hypromellose 6cP, Quinoline yellow (E104) and Carnauba wax (E903).

Losartan/Hydrochlorothiazide Mylan 100 mg/12.5 mg also contains: Hypromellose 6cP

Losartan/Hydrochlorothiazide Mylan 100 mg/25 mg also contains: Hypromellose 15cP, Quinoline yellow (E104).

What Losartan/Hydrochlorothiazide Mylan film-coated tablets looks like and contents of the pack

Losartan/Hydrochlorothiazide Mylan 50 mg/12.5 mg is supplied as yellow, oval, biconvex film-coated tablets, debossed with 'M' on one side of the tablet and 'LH4' on the other side.

Losartan/Hydrochlorothiazide Mylan 100 mg/12.5 mg is supplied as white to off white, oval, biconvex film-coated tablets, debossed with 'M' on one side of the tablet and 'LH5' on the other side.

Losartan/Hydrochlorothiazide Mylan 100 mg/25 mg is supplied as light yellow, oval, biconvex film-coated tablets, debossed with 'M' on one side of the tablet and 'LH6' on the other side.

Losartan/Hydrochlorothiazide Mylan film-coated tablets are supplied in white, opaque blisters in pack sizes of 7, 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100, 112, 280 and 500 tablets, calendar pack of 28 tablets and in white, opaque plastic bottles in pack sizes of 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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 authorised in the Member States of the EEA under the following names:

Austria	Arcalos comp. 50 mg/12,5 mg, 100 mg/12,5 mg, 100 mg/25 mg Filmtabletten
Belgium	Colosamyl 50 mg/12,5 mg, 100 mg/25 mg filmomhulde tabletten
Czech Republic	Losartan/Hydrochlorothiazid Mylan 50 mg/12,5 mg, 100 mg/12,5 mg, potahované tablety
Denmark	Asolzid
Finland	Asolzid
France	LOSARTAN HYDROCHLOROTHIAZIDE MYLAN PHARMA 50 mg/12,5 mg, 100 mg/12,5 mg et 100 mg/25 mg comprimé pelliculé
Germany	Losartan-Kalium comp -dura plus 50 mg/12,5 mg, 100 mg/12,5 mg, 100 mg/25 mg Filmtabletten
Hungary	Losartan HCT Mylan 50 mg/12,5 mg, 100 mg/25 mg filmtabletta
Iceland	Asolzid
Ireland	Losartan/Hydrochlorothiazide Mylan 50mg/12.5mg, 100 mg/12.5 mg and 100 mg/25 mg Tablets
Luxembourg	Colosamyl 50 mg/12,5 mg, 100 mg/25 mg comprimés pelliculés
Norway	Asolzid
Poland	Losacomb
Portugal	LORZIDA

Romania	Lorzitin 50 mg/12,5 mg, 100 mg/12,5 mg, 100 mg/25 mg comprimate filmate
Slovenia	Losartan/hidroklorotiazid Mylan 50 mg/12,5 mg, 100 mg/25 mg filmsko obložene tablete
Spain	Losartan /Hidroclorotiazida MYLAN Pharmaceuticals 50/12,5 mg, 100 mg/25 mg comprimidos recubiertos con película EFG
Sweden	Asolzyd
The Netherlands	Losartankalium/Hydrochloorthiazide Mylan 50/12,5 mg, 100/12,5 mg, 100/25 mg filmomhulde tabletten
United Kingdom	Losartan/Hydrochlorothiazide Mylan 50mg/12.5mg, 100 mg/12,5 mg and 100 mg/25 mg Film-coated Tablets

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