

## Package leaflet: Information for the patient

### Losartan Potassium/Hydrochlorothiazide 100 mg/12.5 mg Film-coated Tablets

(losartan potassium/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 Potassium/Hydrochlorothiazide is and what it is used for
2. What you need to know before you take Losartan Potassium/Hydrochlorothiazide
3. How to take Losartan Potassium/Hydrochlorothiazide
4. Possible side effects
5. How to store Losartan Potassium/Hydrochlorothiazide
6. Contents of the pack and other information

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

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

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

##### Do not take Losartan Potassium/Hydrochlorothiazide

- 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 sulphonamide-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 a blockage, or reduced flow of bile, such as cholestasis (which can be due to impaired liver function or gallstones) causing jaundice, dark urine, pale stools and itching of the skin
- 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 Potassium/Hydrochlorothiazide 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

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

Losartan Potassium/Hydrochlorothiazide 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).

If you have had skin cancer or if you develop an unexpected skin lesion during the treatment.

Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Losartan Potassium/Hydrochlorothiazide

It is important to tell your doctor before taking Losartan Potassium/Hydrochlorothiazide

- if you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking **Losartan Potassium/Hydrochlorothiazide**, seek medical attention immediately.
- 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 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 Losartan Potassium/Hydrochlorothiazide”)
- 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 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 of African or Caribbean descent. You may experience a weaker blood pressure lowering effect of this medicine.
- 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 Potassium/Hydrochlorothiazide”.

- if you are taking other medicines that may increase serum potassium (see section 2 “Other medicines and Losartan Potassium/Hydrochlorothiazide”).

- if you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking Losartan Potassium /Hydrochlorothiazide. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.

### **Other medicines and Losartan Potassium/Hydrochlorothiazide**

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 Potassium/Hydrochlorothiazide may interact with other medicines.

You should avoid taking Losartan Potassium/Hydrochlorothiazide with:

- lithium (used to treat depression),
- potassium supplements, potassium-sparing diuretics (spironolactone, triamterene, amiloride), potassium salts, or other medicines that may increase serum potassium (e.g. trimethoprim-containing medicines)

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

- other medicines to reduce your blood pressure such as ACE-inhibitors (e.g. ramipril), methyldopa
- 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)
- medicines 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)
- sleeping tablets
- opioid medicines such as morphine
- ‘pressor amines’ such as adrenaline or other medicines 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 root and often used in cough medicines) if taken in large amounts.

Also inform your doctor if you are taking Losartan Potassium/Hydrochlorothiazide 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 Potassium/Hydrochlorothiazide” and “Warnings and precautions”).

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

### **Losartan Potassium/Hydrochlorothiazide with food, drink and alcohol**

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

Dietary salt in excessive quantities may counteract the effect of Losartan Potassium/Hydrochlorothiazide tablets. Large amounts of glycyrrhizin which is contained in liquorice and some cough medicines can affect how well Losartan Potassium/Hydrochlorothiazide works.

Grapefruit juice should be avoided while taking Losartan Potassium/ Hydrochlorothiazide.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### **Pregnancy**

Your doctor will normally advise you to stop taking Losartan Potassium/Hydrochlorothiazide before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Losartan Potassium/Hydrochlorothiazide. Losartan Potassium/Hydrochlorothiazide 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**

Losartan Potassium/Hydrochlorothiazide 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 a newborn, or born prematurely.

#### **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.

#### **Losartan Potassium/Hydrochlorothiazide 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 Losartan Potassium/Hydrochlorothiazide**

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 Potassium/Hydrochlorothiazide depending on your condition and whether you are taking other medicines. It is important to continue taking this

medicine for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

### **High Blood Pressure**

The recommended dose for most patients with high blood pressure is 1 tablet of Losartan Potassium/Hydrochlorothiazide 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 50 mg/12.5 mg or changed to 1 tablet daily of 100 mg/25 mg per day. The maximum daily dose is 2 tablets per day of 50 mg/12.5 mg or 1 tablet daily of 100 mg/25 mg.

### **Use in elderly patients**

Losartan Potassium/Hydrochlorothiazide 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 Losartan Potassium/Hydrochlorothiazide in children. Therefore, Losartan Potassium/Hydrochlorothiazide should **not** be given to children.

### **Taking your medicine**

Losartan potassium / Hydrochlorothiazide tablets should be swallowed whole with a glass of water and can be taken with or without food.

### **If you take more Losartan Potassium/Hydrochlorothiazide 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 Losartan Potassium/Hydrochlorothiazide**

Try to take Losartan Potassium/Hydrochlorothiazide daily as prescribed. Do not take a double dose to make up for a forgotten 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 Potassium/Hydrochlorothiazide 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):

- Abnormal kidney function including inflammation of the kidneys and kidney failure.

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

- Angina (chest pain), abnormal heartbeat, cerebrovascular accident (Transient ischaemic attack (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 (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)
- Severe 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).

**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) (anaphylactic reaction)
- Hepatitis (inflammation of the liver).

**Very rare** (may affect up to 1 in 10,000 people):

- acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion)

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

- Unexplained muscle pain with dark (tea-coloured) urine (rhabdomyolysis).
- Skin and lip cancer (Non-melanoma skin cancer).
- Decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion), short-sightedness (acute myopia) or acute angle-closure glaucoma).

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
- Difficulty sleeping (insomnia), headache, dizziness
- Weakness, tiredness, chest pain
- Increased potassium levels (which can cause an abnormal heart rhythm), decreased haemoglobin levels
- Decreased sugar in the blood (hypoglycaemia).

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

- 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), 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 breathlessness, bronchitis, 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
- Hives, itching, inflammation of the skin, rash, redness of the skin, sensitivity to light, dry skin, excessive 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, 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):

- Abnormal liver function tests.

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

- Flu-like symptoms
- 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 Yellow Card Scheme at:

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

## **5. How to store Losartan Potassium/Hydrochlorothiazide**

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 Potassium/Hydrochlorothiazide 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 medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Losartan Potassium/Hydrochlorothiazide film-coated tablets contain**

The active substances are losartan potassium and hydrochlorothiazide. Each tablet contains 100 mg of losartan potassium and 12.5 mg of hydrochlorothiazide.

The other ingredients are: cellulose microcrystalline, lactose monohydrate (see section 2 “Losartan Potassium/Hydrochlorothiazide contains lactose”), starch pregelatinized (maize), magnesium stearate, hydroxypropyl cellulose and titanium dioxide.

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

### **What Losartan Potassium/Hydrochlorothiazide film-coated tablets look like and contents of the pack**

Losartan Potassium/Hydrochlorothiazide 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 Potassium/Hydrochlorothiazide 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 opaque plastic bottles in pack sizes of 100 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder:**

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

### **Manufacturers:**

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

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

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

**This leaflet was last revised in May 2023.**