**Package leaflet: Information for the patient**

# LOSARTAN POTASSIUM/HYDROCHLOROTHIAZIDE MSD 50mg/12.5mg film-coated Tablets
# LOSARTAN POTASSIUM/HYDROCHLOROTHIAZIDE MSD 100mg/12.5mg film-coated Tablets
# LOSARTAN POTASSIUM/HYDROCHLOROTHIAZIDE MSD 100mg/25mg film-coated Tablets
**losartan potassium and hydrochlorothiazide**

**Read all of this leaflet carefully before 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, pharmacist, or nurse.
- 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, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**


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

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

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

**Do not take Losartan Potassium/Hydrochlorothiazide MSD**
- 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 Potassium/Hydrochlorothiazide MSD 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, pharmacist, or nurse before taking Losartan Potassium/Hydrochlorothiazide MSD.

You must tell your doctor if you think you are (or might become) pregnant. Losartan Potassium/Hydrochlorothiazide MSD 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 Potassium/Hydrochlorothiazide MSD**:**
- 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 Potassium/Hydrochlorothiazide MSD");
- 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 Potassium/Hydrochlorothiazide MSD**".

**Children and adolescents**
There is no experience with the use of Losartan Potassium/Hydrochlorothiazide MSD in children. Therefore, Losartan Potassium/Hydrochlorothiazide MSD should not be given to children.

**Other medicines and Losartan Potassium/Hydrochlorothiazide MSD**
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 MSD may interact with other medicines.

Preparations containing lithium should not be taken with Losartan Potassium/Hydrochlorothiazide MSD 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, 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 colestyramine;
- 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.

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 MSD**" and "**Warnings and precautions**").

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

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

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

Losartan Potassium/Hydrochlorothiazide MSD 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 Potassium/Hydrochlorothiazide MSD 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 MSD. Losartan Potassium/Hydrochlorothiazide MSD 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 Potassium/Hydrochlorothiazide MSD is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed.

**Use in elderly patients**
Losartan Potassium/Hydrochlorothiazide MSD 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 Potassium/Hydrochlorothiazide MSD 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 Potassium/Hydrochlorothiazide MSD

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

**High Blood Pressure**
The usual dose of Losartan Potassium/Hydrochlorothiazide MSD for most patients with high blood pressure is 1 tablet of Losartan Potassium/Hydrochlorothiazide MSD 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 50 mg/12.5 mg Film-Coated Tablets or changed to 1 tablet daily of Losartan / Hydrochlorothiazide 100 mg/25 mg Film-Coated Tablets (a stronger strength) per day. The maximum daily dose is 2 tablets per day of Losartan / Hydrochlorothiazide 50 mg/12.5 mg Film-Coated Tablets or 1 tablet daily of Losartan / Hydrochlorothiazide 100 mg/25 mg Film-Coated Tablets.

**Administration**
The tablets should be swallowed whole with a glass of water.

**If you take more Losartan Potassium/Hydrochlorothiazide MSD 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 Potassium/Hydrochlorothiazide MSD**
Try to take Losartan Potassium/Hydrochlorothiazide MSD daily as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule.

## 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 Losartan Potassium/Hydrochlorothiazide MSD 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:

*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, 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, reduction in white blood cells, clotting problems, 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 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, angina (chest pain), abnormal heartbeat, cerebrovascular accident (TIA, "mini-stroke"), heart attack, palpitations;
- inflammation of blood vessels, which is often associated with a skin rash or bruising;
- sore throat, breathlessness, bronchitis, pneumonia, water on the lungs (which causes difficulty breathing), nosebleed, runny nose, congestion;
- constipation, obstipation, wind, 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;
- 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):*
- hepatitis (inflammation of the liver), 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, pharmacist, or nurse. 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 Potassium/Hydrochlorothiazide MSD

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 container. The expiry date refers to the last day of that month.

Blisters
Store Losartan Potassium/Hydrochlorothiazide MSD in the original package in order to protect from light and moisture. Do not store the package above 30°C.

Bottle
Store in the original container in order to protect from light. Keep the bottle tightly closed in order to protect from moisture. Do not store the bottle above 25°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 Losartan Potassium/Hydrochlorothiazide MSD contains**

The active substances are losartan potassium and hydrochlorothiazide.

Losartan Potassium/Hydrochlorothiazide MSD 50 mg/12.5 mg contains 50 mg of losartan potassium and 12.5 mg of hydrochlorothiazide as the active ingredients.

Losartan Potassium/Hydrochlorothiazide MSD100 mg/12.5 mg contains 100 mg of losartan potassium and 12.5 mg of hydrochlorothiazide as the active ingredients.

Losartan Potassium/Hydrochlorothiazide MSD 100 mg/25 mg contains 100 mg of losartan potassium and 25 mg of hydrochlorothiazide as the active ingredients.

Losartan Potassium/Hydrochlorothiazide MSD 50 mg/12.5 mg, Losartan Potassium/Hydrochlorothiazide MSD 100 mg/12.5 mg and Losartan Potassium/Hydrochlorothiazide MSD 100 mg/25 mg contain the following inactive ingredients:
microcrystalline cellulose (E460), lactose monohydrate, pregelatinized maize starch, magnesium stearate (E572), hydroxypropyl cellulose (E463), hypromellose (E464).

Losartan Potassium/Hydrochlorothiazide MSD 50 mg/12.5 mg contains 4.24 mg (0.108 mEq) of potassium. Losartan Potassium/Hydrochlorothiazide MSD 100 mg/12.5 mg and Losartan Potassium/Hydrochlorothiazide MSD 100 mg/25 mg contain 8.48 mg (0.216 mEq) of potassium.

Losartan Potassium/Hydrochlorothiazide MSD 50 mg/12.5 mg and Losartan Potassium/Hydrochlorothiazide MSD 100 mg/25 mg also contain titanium dioxide (E171), quinoline yellow aluminum lake (E104) and carnauba wax (E903).

Losartan Potassium/Hydrochlorothiazide MSD 100 mg/12.5 mg also contains: Titanium dioxide (E171) and Carnauba wax (E903).

**What Losartan Potassium/Hydrochlorothiazide MSD looks like and contents of the pack**

Losartan Potassium/Hydrochlorothiazide MSD 50 mg/12.5 mg is supplied as yellow, oval film-coated tablets marked 717 on one side and plain or scored on the other. The score line is not intended for breaking the tablet..

Losartan Potassium/Hydrochlorothiazide MSD 100 mg/12.5 mg is supplied as white, oval film-coated tablets marked 745 on one side and plain on the other.

Losartan Potassium/Hydrochlorothiazide MSD 100 mg/25 mg is supplied as light yellow, oval film-coated tablets marked 747 on one side and plain on the other.

Losartan Potassium/Hydrochlorothiazide MSD is supplied in the following pack sizes:
Losartan Potassium/Hydrochlorothiazide MSD 50 mg/12.5 mg>- PVC/PE/PVDC blister packages with aluminum foil lidding in cartons containing 4, 7, 10, 14, 20, 28, 30, 50, 56, 84, 90, 98, or 280 tablets. HDPE bottles of 100 tablets.

Losartan Potassium/Hydrochlorothiazide MSD 100 mg/12.5 mg - PVC/PE/PVDC blister packages with aluminum foil lidding in cartons containing 14, 15, 28, 30, 50, 56, 84, 90, 98, 280 tablets. HDPE bottles of 100 tablets.

Losartan Potassium/Hydrochlorothiazide MSD 100 mg/25 mg - PVC/PE/PVDC blister packages with aluminum foil lidding in cartons containing 7, 14, 28, 30, 50, 56, 84, 90, 98, or 280 tablets. HDPE bottles of 100 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Merck Sharp & Dohme Ireland (Human Health) Ltd, Red Oak North, South County Business Park, Leopardstown, Dublin 18, Ireland.

**Manufacturers:**
**50 mg/12.5 mg strength:** Merck Manufacturing Division, Shotton Lane, Cramlington, Northumberland, NE23 3JU, UK.
**100 mg/12.5 mg and 100 mg/25 mg strengths:** Merck Sharp & Dohme BV, Waarderweg 39, 2031 BN, Haarlem, Netherlands.

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

Austria
Losartan/Hydrochlorothiazid MSD

France
LOSARTAN HYDROCHLOROTHIAZIDE ZENTIVA

Ireland
Losartan Potassium/Hydrochlorothiazide MSD 50 mg/12.5 mg film-coated tablets
Losartan Potassium/Hydrochlorothiazide MSD 100 mg/12.5 mg film-coated tablets
Losartan Potassium/Hydrochlorothiazide MSD 100 mg/25 mg film-coated tablets

Netherlands
LOSARTAN POTASSIUM/HYDROCHLOROTHIAZIDE MSD

**50 mg /12,5 mg 100 mg/12,5 mg 100 mg/25 mg**

**This leaflet was last revised in October 2017**