

CO-LOSAR® 50 mg / 12, 5 mg

Losartan potassium 50 mg / Hydrochlorothiazide 12,5 mg

CO-LOSAR PLUS® 100 mg / 12,5 mg

Losartan potassium 100 mg / Hydrochlorothiazide 12,5 mg

CO-LOSAR FORT® 100 mg / 25 mg

Losartan potassium 100 mg / Hydrochlorothiazide 25 mg

Please read carefully the integrity of this notice before taking this drug.
 - Keep this notice; you may need to read it again.
 - If you have further questions, if you have any doubt, ask your doctor or pharmacist for more information.
 - This was prepared for you personally. Never give it to someone else, even in case of identical symptoms; this could be harmful for this person.
 - If one of the undesirable effects worsens or if you experience an undesirable effect which is not mentioned in this notice, inform your doctor or your pharmacist.

In this notice:

1. What is CO-LOSAR®, CO-LOSAR PLUS® and CO-LOSAR FORT® and in which case is it used?
2. What is necessary to know before taking CO-LOSAR®, CO-LOSAR PLUS® and CO-LOSAR FORT® ?
3. How to use CO-LOSAR®, CO-LOSAR PLUS® and CO-LOSAR FORT® ?
4. What are the eventual undesirable effects?
5. How to store CO-LOSAR®, CO-LOSAR PLUS® and CO-LOSAR FORT® ?
6. Further information

1. WHAT IS CO-LOSAR®, CO-LOSAR PLUS® AND CO-LOSAR FORT® AND IN WHICH CASE IS IT USED ?
 CO-LOSAR® (LOSARTAN POTASSIUM) and CO-LOSAR FORT® are 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.

Therapeutic indications:
 CO-LOSAR®: Treatment of the essential hypertension when a monotherapy with an angiotensin II antagonist is insufficient.
 CO-LOSAR PLUS®: Treatment of essential hypertension in case of inadequate blood pressure control with losartan potassium at a dose of 100 mg/day.
 CO-LOSAR FORT®: Treatment of essential hypertension in case of inadequate blood pressure control in the combination of losartan potassium (at a dose of 50 mg/day) and hydrochlorothiazide (at a dose of 12.5 mg/day).
2. WHAT IS NECESSARY TO KNOW BEFORE TAKING CO-LOSAR®, CO-LOSAR PLUS® AND CO-LOSAR FORT® ?
 Do not take CO-LOSAR®, CO-LOSAR PLUS® and CO-LOSAR FORT® if:
 - If you are allergic (hypersensitive) to losartan, hydrochlorothiazide or to any of the other ingredients in this medicine;
 - If you are allergic (hypersensitive) to other sartans/imidazole-derived substances (e.g. other thiazides, some antihistaminic drugs such as cetirizine, ask your doctor if you are not sure);
 - If you are more than 3 months pregnant. (It is also better to avoid CO-LOSAR®, CO-LOSAR PLUS® or CO-LOSAR FORT® during pregnancy and breastfeeding, namely pregnancy);
 - If you have severely impaired liver function;
 - 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 cannot be corrected by treatment;
 - If you are suffering from gout.
Take special care CO-LOSAR®, CO-LOSAR PLUS® and CO-LOSAR FORT®
 Directly inform your doctor if you think you are (or might become) pregnant.
 CO-LOSAR®, CO-LOSAR PLUS® and CO-LOSAR FORT® are 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 section: Pregnancy and breastfeeding, para 6.2).
 It is important to tell your doctor before taking CO-LOSAR®, CO-LOSAR PLUS® or CO-LOSAR FORT®:
 - 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: Do not take CO-LOSAR®, CO-LOSAR PLUS® and CO-LOSAR FORT®);
 - 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 a disease of the heart muscle (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).

Other drugs:
 Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
 Diuretic agents such as the hydrochlorothiazide contained in CO-LOSAR®, CO-LOSAR PLUS® and CO-LOSAR FORT® may interact with other medicines.
 Preparations containing lithium should not be taken with CO-LOSAR®, CO-LOSAR PLUS® or CO-LOSAR FORT® 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, some laxatives, medicines for the treatment of gout, medicines to control heart rhythm or other drugs (e.g. insulin).
 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 insulin.

Please also inform your doctor if you are taking CO-LOSAR®, CO-LOSAR PLUS® or CO-LOSAR FORT® and you will be undergoing a radiographic procedure and will be given iodine contrast media.
Food and drinks:
 You are advised not to drink alcohol whilst taking these tablets: alcohol and CO-LOSAR®, CO-LOSAR PLUS® or CO-LOSAR FORT® may increase each other's effects.
 Dietary salt in excessive quantities may counteract the effect of CO-LOSAR®, CO-LOSAR PLUS® or CO-LOSAR FORT®.
 CO-LOSAR®, CO-LOSAR PLUS® or CO-LOSAR FORT® may be taken with or without food.

Pregnancy and breastfeeding:
Pregnancy:
 You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking CO-LOSAR®, CO-LOSAR PLUS® or CO-LOSAR FORT® before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of CO-LOSAR®, CO-LOSAR PLUS® or CO-LOSAR FORT®.
Breast-feeding:
 Tell your doctor if you are breast-feeding or about to start breast-feeding. CO-LOSAR®, CO-LOSAR PLUS® or CO-LOSAR FORT® 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 children and adolescents:
 There is no experience with the use of CO-LOSAR®, CO-LOSAR PLUS® or CO-LOSAR FORT® in children. Therefore, CO-LOSAR®, CO-LOSAR PLUS® and CO-LOSAR FORT® should not be given to children.
Use in elderly patients:
 CO-LOSAR®, CO-LOSAR PLUS® and CO-LOSAR FORT® 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.

Spontaneous and approved:
 The diuretic contained in this medicine may produce a positive test carried out in the doping control.
Driving and machines use:
 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.
Important information about some of the ingredients of CO-LOSAR®, CO-LOSAR PLUS® and CO-LOSAR FORT®:
 CO-LOSAR®, CO-LOSAR PLUS® and CO-LOSAR FORT® contain 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 USE CO-LOSAR®, CO-LOSAR PLUS® AND CO-LOSAR FORT® ?

Dosage:
 CO-LOSAR®: The usual dose of CO-LOSAR® permitting to control blood pressure is one tablet per day. The maximal antihypertensive effect is reached within the 3 weeks following the initiation of the treatment.
 CO-LOSAR PLUS®: The usual dose of CO-LOSAR PLUS® permitting to control blood pressure is one tablet per day, in case of inadequate blood pressure control;
 in association with losartan potassium at a dose of 100 mg/day;
 - or, with the combination of losartan potassium (at a dose of 50 mg/day) and hydrochlorothiazide (at a dose of 12.5 mg/day).
 Generally, the maximal antihypertensive effect is reached within the 3 weeks following the initiation of the treatment.
 CO-LOSAR FORT®: For patients who do not respond adequately to the association losartan potassium (at a dose of 50mg/day) and hydrochlorothiazide (at a dose of 12.5 mg/day) after at least 3 weeks, the dose may be increased to 1 tablet per day of CO-LOSAR FORT®. A daily dosage higher than 2 tablets is not recommended.

*** Mode of administration**

Oral intake.
 CO-LOSAR®, CO-LOSAR PLUS® or CO-LOSAR FORT® can be taken during or between meals times. Practically, and in aim to help you to remember, try to take CO-LOSAR®, CO-LOSAR PLUS® or CO-LOSAR FORT® each day at the same moment. Hypertension is a chronic disease which requires a prolonged treatment.

*** Treatment duration:**

In all cases, strictly comply with your doctor's prescription.
 If you have used more CO-LOSAR®, CO-LOSAR PLUS® and CO-LOSAR FORT® 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 forgot to use CO-LOSAR®, CO-LOSAR PLUS® and CO-LOSAR FORT®
 Try to take CO-LOSAR®, CO-LOSAR PLUS® or CO-LOSAR FORT® daily as prescribed. However, if you miss a dose, do not take an extra dose, just resume your usual schedule.

4. WHAT ARE THE EVENTUAL UNDESIRABLE EFFECTS?

Like all medicines, CO-LOSAR®, CO-LOSAR PLUS® or CO-LOSAR FORT® can cause side effects, although not everybody gets them.
 If you experience the following, stop taking CO-LOSAR®, CO-LOSAR PLUS® or CO-LOSAR FORT® and tell your doctor immediately so that the cause of the symptoms can be determined by 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 you may not take an extra dose, just resume your usual schedule.

The following side effects have been reported:
Common (affecting less than one person in 10 but more than one person in 100):
 - 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 disrupt heart rhythm), decreased haemoglobin levels;
 - Changes in kidney function including kidney failure;
 - decrease of sugar in the blood (hypoglycaemia).

Uncommon (affecting less than one person in 100 but more than one person in 1,000):
 - Ataxia, red or brownish spots on the skin (sometimes especially on the feet, legs, arms and buttocks, with joint pain, blurred vision, burning or stinging in the eyes, conjunctivitis, worsening eyesight, seeing things in yellow;
 - 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 heartbeats, 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 upset, 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 (more than 1 out of 10,000 patients but less than 1 out of 100,000 patients):
 Hepatitis (inflammation of the liver), abnormal liver function tests.
Not known
 - Flu-like symptoms;
 - Unexplained muscle pain with dark (tea-colored) urine (rhabdomyolysis);
 - Low level of sodium in the blood (hyponatraemia);
 - Generally feeling unwell (malaise).

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE CO-LOSAR®, CO-LOSAR PLUS® and CO-LOSAR FORT® ?

Keep out of the reach and sight of children.
 To be stored at temperature below 30 °C.

6. FURTHER INFORMATION

What does CO-LOSAR®, CO-LOSAR PLUS® and CO-LOSAR FORT® contain:

	CO-LOSAR® 50 mg/12,5 mg	CO-LOSAR PLUS® 100 mg/12,5 mg	CO-LOSAR FORT® 100 mg/25 mg
Losartan potassium	50 mg	100 mg	100 mg
Hydrochlorothiazide	12,5 mg	12,5 mg	25 mg
Excipients	Microcrystalline cellulose, pregelatinized corn starch, croscarmellose sodium, lactose monohydrate, magnesium stearate, OPADRY II yellows,q,f one tablet	Microcrystalline cellulose, pregelatinized corn starch, croscarmellose sodium, lactose monohydrate, magnesium stearate, colloidal anhydrous silica, OPADRY II oranges,q,f one tablet	Microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, magnesium stearate, OPADRY II yellows,q,f one tablet
Active excipients	lactose monohydrate		

What is CO-LOSAR®, CO-LOSAR PLUS® et CO-LOSAR FORT® and external packaging content :

Specialities	Form	M.A. N°	Presentations
CO-LOSAR 50 mg / 12,5 mg	round, yellow coated tablet-Alu/ white PVC blister	923 342 1	Box of 30 tablets
		923 342 2	Box of 60 tablets
CO-LOSAR FORT 100 mg / 25 mg	oblong, scored, yellow coated tablet-Alu/ white PVC blister	923 342 3	Box of 90 tablets
		923 380 1	Box of 30 tablets
CO-LOSAR PLUS 100 mg / 12,5 mg	oblong, scored, orange coated tablet-Alu/ white PVC blister	923 380 2	Box of 60 tablets
		923 380 3	Box of 90 tablets
CO-LOSAR PLUS 100 mg / 12,5 mg	oblong, scored, orange coated tablet-Alu/ white PVC blister	923 378 1	Box of 30 tablets
		923 378 2	Box of 90 tablets

Delivery conditions:

Tablet A, list I. Only on medical prescription.
Marketing Authorization holder and manufacturer
 Les Laboratoires MEDIS - S.A.
 Route de Nabeul - KM 7 - BP 206 800 Nabeul - Tunisie
 Tel : (216) 72 27 00 06 ; Fax: (216) 72 23 50 16
Last approved date of this notice : March 2016

This is a drug

- A drug is a specific product agent.
- A drug is a product acting on your health and its use, contrary to prescriptions may be dangerous for you.
- Strictly respect the doctor's prescription and the instructions of use he has prescribed.
- Follow your pharmacist's know this drug ; its indications and contra-indications.
- Do not discontinue the drug intake by yourself during the prescription period.
- Do not repeat the prescription or increase the dosage without consulting your doctor.

KEEP ANY DRUG OUT OF THE REACH OF CHILDREN.

Les Laboratoires MEDIS - S.A.
 Route de Tunis KM 7 - BP206 - 8000 Nabeul - Tunisie
 Tél. (216) 72 235 006 Fax: (216) 72 235 106