PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACIST'S REGULATIONS (PREPARATIONS) – 1986

This medicine can be sold under doctor's prescription only

OCSAAR® PLUS
Tablets

Each tablet contains:
Losartan Potassium 50 mg
Hydrochlorothiazide 12.5 mg

For a list of inactive ingredients please refer to section 6.

Read all of this leaflet carefully before you start using this medicine.
- This leaflet contains concise information about **OCSAAR PLUS**. If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their ailment seems similar to yours.

OCSAAR PLUS is not intended for children and adolescents under 18 years of age.

1. WHAT IS THIS DRUG INTENDED FOR?
OCSAAR PLUS is intended for the treatment of hypertension, and to help lower the risk of stroke in patients with high blood pressure and a thickening of the left ventricle (the heart's main pumping chamber).
THERAPEUTIC GROUP: OCSAAR PLUS is a combination of an angiotensin II receptor antagonist (losartan) and a thiazide diuretic (hydrochlorothiazide).

2. BEFORE YOU TAKE OCSAAR PLUS
Do not take OCSAAR PLUS if you:
- are allergic to losartan, hydrochlorothiazide or to any of the other ingredients of this medicine (see further information in section 6),
- 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),
- have severely impaired liver function,
- have low potassium, low sodium or high calcium levels which cannot be corrected by treatment,
- are suffering from gout,
- are more than 3 months pregnant. (It is also better to avoid **OCSAAR PLUS** in early pregnancy, see section "Pregnancy and breast-feeding"),
- have severely impaired kidney function or your kidneys are not producing any urine,
- have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Special warnings concerning use of OCSAAR PLUS
Talk to your doctor, pharmacist, or nurse before taking the medicine.
You must tell your doctor if you think you are (or might become) pregnant. **OCSAAR PLUS** is not recommended in early pregnancy, and must not be taken if you are in the 2nd and 3rd trimester of pregnancy, as it may cause serious harm to your baby if used at that stage (see section "Pregnancy and breast-feeding").
Before treatment with **OCSAAR PLUS**, it is important to tell your doctor if:
- you have previously suffered from swelling of the face, lips, throat or tongue
- you take diuretics ("water pills")
- you are on a salt-restricted diet
- you have or have had severe vomiting and/or diarrhoea
- you have heart failure
- your liver function is impaired (see section 2 "Do not take **OCSAAR PLUS** if you")
- you have narrow arteries to your kidneys (renal artery stenosis) or only have one functioning kidney, or you have recently had a kidney transplant

- you have narrowing of the arteries (atherosclerosis), angina pectoris (chest pain due to poor heart function)
- you have 'aortic or mitral valve stenosis' (narrowing of the valves of the heart) or 'hypertrophic cardiomyopathy' (a disease causing thickening of heart muscle)
- you are diabetic
- you have had gout
- you have or have had an allergic condition, asthma or a condition that causes joint pain, skin rashes and fever (systemic lupus erythematosus)
- you have high calcium or low potassium levels or you are on a low potassium diet
- 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 **OCSAAR PLUS** tablets
- you suffer from primary hyperaldosteronism (a syndrome caused by an abnormality within the adrenal gland and associated with increased secretion of the hormone aldosterone by the gland)
- 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.
- 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 **OCSAAR PLUS**.

See also information under the heading "Do not take **OCSAAR PLUS** if you".

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, you should inform the attending doctor or pharmacist.
Diuretic agents such as the hydrochlorothiazide contained in **OCSAAR PLUS** may interact with other medicines.
Preparations containing lithium should not be taken with **OCSAAR PLUS** 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 heading "**Do not take OCSAAR PLUS if you**" and "**Special warnings concerning use of OCSAAR PLUS**")

Please inform your doctor you are taking **OCSAAR PLUS** if you will also be undergoing a radiographic procedure and will be given iodine contrast media.

Taking the medicine and food
Dietary salt in excessive quantities may counteract the effect of **OCSAAR PLUS** tablets.
OCSAAR PLUS tablets may be taken with or without food.

Taking the medicine and alcohol consumption
You are advised not to drink alcohol whilst taking these tablets: alcohol and **OCSAAR PLUS** tablets may increase each other's effects**.**

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 **OCSAAR PLUS** before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of **OCSAAR PLUS**. **OCSAAR PLUS** is not recommended during pregnancy, and must not be taken in the 2nd and 3rd trimester of pregnancy, 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. **OCSAAR PLUS** 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 children
There is no experience with the use of **OCSAAR PLUS** in children. Therefore, **OCSAAR PLUS** should not be given to children.

Use in the elderly
OCSAAR PLUS 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.

Important information about some of the ingredients of OCSAAR PLUS
OCSAAR PLUS tablets contain potassium (for potassium content, please refer to section 6).
OCSAAR PLUS tablets contain lactose (for lactose content, please refer to section 6).
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 DO YOU USE OCSAAR PLUS?
Always take **OCSAAR PLUS** as instructed by the doctor. You should check with your doctor or pharmacist if you are not sure.
It is important to continue taking **OCSAAR PLUS** for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

OCSAAR PLUS can be taken with or without food. Swallow the medicine with a small amount of water.
The dosage and method of treatment will be determined by the physician only.
The usually recommended dosage is:
High Blood Pressure
The usual dose of **OCSAAR PLUS** for most patients with high blood pressure is 1 tablet of **OCSAAR PLUS** per day to control blood pressure over the 24 hour period. The maximum daily dose is 2 tablets per day of **OCSAAR PLUS** once daily.
Patients with high blood pressure and a thickening of the left ventricle
The dosage will be determined by the physician only.

Do not exceed the recommended dose.

The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

If you take more OCSAAR PLUS than you should
Overdose can cause a drop in blood pressure, palpitations, slow pulse, changes in blood composition, and dehydration.
If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

If you forget to take OCSAAR PLUS
Try to take **OCSAAR PLUS** daily as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule.
Continue the treatment as recommended by your doctor.

How can you contribute to the success of the treatment?
It is important to continue taking **OCSAAR PLUS** for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.
Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. SIDE EFFECTS
Like all medicines, **OCSAAR PLUS** can cause side effects, in some of the users.
Do not be alarmed by reading the list of side effects, you may not suffer from any of them.
Stop taking the medicine and proceed immediately to the doctor or to the nearest emergency room if the following appears:
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 appears in a frequency of 1-10 patients out of 10,000. 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)
- Skin and lip Cancer (Non-melanoma skin cancer)

If a side effect occurs, if any of the side effects gets serious or if you notice any side effects not mentioned in this leaflet, consult your doctor.

Reporting of side effects
Side effects can be reported to the Ministry of Health by using the link "Adverse Drug Reactions Report" at the home page of the Ministry of Health's web site (www.health.gov.il) which refers to the online side effects reporting form, or by using the link:
https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. HOW TO STORE OCSAAR PLUS?
Avoid poisoning! This medicine, as all other medicine, must be stored in a safe place out of the reach of children and/or infants, in order to avoid poisoning.
Do not use **OCSAAR PLUS** after the expiry date (exp. date) which is stated on pack. The expiry date refers to the last day of the indicated month.
Do not store above 30ºC. Store in the original package in order to protect from light and moisture.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION
In addition to the active ingredients this medicine also contains:
Microcrystalline cellulose, lactose monohydrate, pregelatinized maize starch, magnesium stearate, hydroxypropyl cellulose, hypromellose, titanium dioxide, quinoline yellow aluminum lake, carnauba wax.

OCSAAR PLUS contains potassium in the following amount: 4.24 mg (0.108 mEq).
OCSAAR PLUS contains lactose monohydrate in the following amount: 63.13 mg.

What OCSAAR PLUS looks like and contents of the pack
OCSAAR PLUS is a yellow, oval, film-coated tablet with “717” debossed on one side and scored on the other.

Pack sizes:
OCSAAR PLUS TABLETS: 30 tablets per pack.

Manufacturer:
Merck Sharp & Dohme, B.V., Haarlem, The Netherlands.

Marketing authorization holder:

Merck Sharp & Dohme (Israel-1996) Company Ltd., P.O. Box 7121, Petah-Tikva 49170.

This Leaflet was checked and approved by the Ministry of Health in July 2016 and was updated according to the Ministry of Health instruction in March 2019.

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