

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

This medicine is to be supplied under doctor's prescription only

## **OCSAAR<sup>®</sup> PLUS**

### **Tablets**

#### **Each tablet contains:**

Losartan Potassium 50 mg

Hydrochlorothiazide 12.5 mg

For a list of inactive and allergenic ingredients see section "Important information about some of the ingredients of **OCSAAR PLUS**" and section 6 "FURTHER INFORMATION".

#### **Read the entire 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 OCSAAR PLUS IS INTENDED FOR?**

**OCSAAR PLUS** is intended for the treatment of hypertension, and to reduce 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).

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.

### **2. BEFORE YOU TAKE OCSAAR PLUS**

#### **Do not take OCSAAR PLUS if you:**

- are allergic (hypersensitive) to losartan, hydrochlorothiazide or to any of the other ingredients of this medicine (listed 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 or pharmacist before taking **OCSAAR PLUS**.

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 **OCSAAR PLUS**. 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.

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 more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see "Pregnancy and breast-feeding" section).

It is important to tell your doctor before taking **OCSAAR PLUS** 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 **OCSAAR PLUS**, seek medical attention immediately;
- 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 associated with increased secretion of the hormone aldosterone by the adrenal gland, caused by an abnormality within 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.

See also information under the heading “Do not take **OCSAAR PLUS** if you”;

- you are taking other medicines that may increase serum potassium (see section 2 “Drug interactions”).
- 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**.

### Drug interactions

**If you are taking, have recently taken, or might take other medicines, including non-prescription medicines and nutritional supplements, you should inform the attending doctor or pharmacist.**

Tell your doctor if you are taking potassium supplements, potassium-containing salt substitutes, potassium-sparing medicines, or other medicines that may increase serum potassium (e.g., trimethoprim-containing medicines), as the combination with **OCSAAR PLUS** is not advisable.

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 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 **OCSAAR PLUS** if you” and “Special warnings concerning use of **OCSAAR PLUS**”).

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

### **Taking OCSAAR PLUS with food and drink**

Dietary salt in excessive quantities may counteract the effect of **OCSAAR PLUS** tablets.

**OCSAAR PLUS** tablets may be taken with or without food.

Grapefruit juice should be avoided while taking **OCSAAR PLUS** tablets.

### **Taking OCSAAR PLUS 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 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. **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.

### **Children and adolescents**

There is no experience with the use of **OCSAAR PLUS** in children. Therefore, **OCSAAR PLUS** should not be given to children.

### **Use in elderly patients**

**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 TO TAKE OCSAAR PLUS?**

Always take **OCSAAR PLUS** as instructed by the doctor. You should check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

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.

The tablets should be swallowed with a glass 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 score line is not intended for breaking the tablet.

No information is available regarding crushing/chewing/splitting of the tablets.

#### **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.

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 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.

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

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

Other side effects that may occur:

*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-coloured) 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);
- 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) or acute angle-closure glaucoma).

**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 "Reporting side effects due to medicinal treatment" at the home page of the Ministry of Health's web site ([www.health.gov.il](http://www.health.gov.il)) which refers to the online side effects reporting form, or by using the link: <https://sideeffects.health.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 and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use **OCSAAR PLUS** after the expiry date (exp. date) which is stated on the pack. The expiry date refers to the last day of the indicated month.

Do not store above 30°C. 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, hydroxypropyl cellulose, hypromellose, magnesium stearate, 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:** 10 or 30 tablets per pack.

Not all pack sizes may be marketed.

**Manufacturer:** Organon LLC, NJ USA

**License holder and address:**

Organon Pharma Israel Ltd., 1 Atir Yeda, Kfar Saba

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**Drug registration no. listed in the official registry of the Ministry of Health:** 111.23.29411