

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

The medicine is dispensed with a doctor's prescription only

SECTOR 50

Film-coated Tablets

The active ingredient:

Each film-coated tablet contains:
sacubitril 24 mg
and valsartan 26 mg as a sodium salt complex

SECTOR 100

Film-coated Tablets

The active ingredient:

Each film-coated tablet contains:
sacubitril 49 mg
and valsartan 51 mg as a sodium salt complex

SECTOR 200

Film-coated Tablets

The active ingredient:

Each film-coated tablet contains:
sacubitril 97 mg
and valsartan 103 mg as a sodium salt complex

For the list of inactive and allergenic ingredients in the preparation see section 2 "Important information regarding some of the ingredients of the medicine" and section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Sector is intended for heart failure patients (NYHA stage II-IV) in patients with a systolic problem.

Sector reduces cardiovascular mortality rate and hospitalizations due to heart failure to a greater degree than angiotensin-converting enzyme (ACE) inhibitors.

Therapeutic group:

Sector belongs to a group of preparations that act on the renin-angiotensin system; angiotensin II receptor blockers (ARBs), different combinations.

Heart failure occurs when the heart is weak and is not capable of pumping enough blood to the lungs and the rest of the body. The most common symptoms of heart failure are breathlessness, fatigue and ankle swelling.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredients sacubitril, valsartan or to any of the additional ingredients contained in the medicine (listed in section 6 “Further information”).
- You are taking another type of medicine called an angiotensin-converting enzyme (ACE) inhibitor (for example, enalapril, lisinopril or ramipril), which is used to treat high blood pressure or heart failure. If you took an ACE inhibitor, wait for 36 hours after taking the last dose before starting treatment with **Sector** (also see “Drug interactions” section).
- You have suffered in the past from a condition called angioedema (rapid spreading of swelling under the skin in areas such as the face, throat, arms and legs which can be life-threatening if throat swelling blocks the airways) when taking an ACE inhibitor or an angiotensin receptor blocker (ARB) (such as valsartan, telmisartan or irbesartan).
- You have a history of angioedema which is hereditary or for which the cause is unknown (idiopathic).
- You have diabetes or impaired kidney function and you are being treated with a blood pressure-lowering medicine containing aliskiren (also see “Drug interactions” section).
- You suffer from a severe liver disease.
- You are more than 3 months pregnant (see “Pregnancy, breastfeeding and fertility” section).

If any of the above conditions apply to you, do not take Sector and inform the doctor.

Special warnings regarding use of the medicine

Before starting and during the course of treatment with Sector, tell the doctor if:

- You are being treated with an angiotensin receptor blocker (ARB) or aliskiren (see section “Do not use the medicine if”).
- You suffered in the past from angioedema (see section “Do not use the medicine if” and section 4 “Side effects”).
- You have low blood pressure or are taking other medicines that reduce blood pressure (for example, medicines that increase urine production (diuretics)) or are suffering from vomiting or diarrhea, especially if you are aged 65 years or more, or if you suffer from a kidney disease and low blood pressure.
- You suffer from a kidney disease.
- You suffer from dehydration.
- Your kidney artery has narrowed.

- You suffer from a liver disease.
- You have hallucinations, paranoia or sleep pattern changes while taking **Sector**.
- Your systolic blood pressure is lower than 100 mmHg.
- You have hyperkalemia (high blood potassium levels).
- You suffer from heart failure classified as NYHA class IV (unable to carry out any physical activity without discomfort and may have symptoms even when resting).

If any of the above conditions apply to you, tell the doctor or pharmacist before taking Sector.

Children and adolescents

The medicine is not intended for children and adolescents under 18 years of age.

Tests and follow-up

Your doctor may check your blood potassium and sodium levels at regular intervals during the course of treatment with **Sector**.

In addition, your doctor may check your blood pressure at the start of treatment and when the dose is increased.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. It may be necessary to change the dose, to take precautions, or even to stop taking one of the medicines. This is particularly important for the following medicines:

- ACE inhibitors. Do not take **Sector** with ACE inhibitors. If you took an ACE inhibitor, wait 36 hours after taking the last dose of the ACE inhibitor before starting treatment with **Sector** (see section “Do not use the medicine if”). If you stop taking **Sector**, wait 36 hours after taking the last dose of **Sector** before starting treatment with an ACE inhibitor.
- Other medicines used to treat heart failure or lower blood pressure, such as angiotensin receptor blockers or aliskiren (see section “Do not use the medicine if”).
- Certain medicines from the statins group that are used to lower high cholesterol levels (for example, atorvastatin).
- Sildenafil, tadalafil, vardenafil or avanafil, medicines used to treat impotence or pulmonary hypertension.
- Medicines that increase the amount of potassium in the blood, including potassium supplements, salt substitutes containing potassium, potassium-sparing medicines and heparin.
- Non-steroidal anti-inflammatory drugs (NSAIDs) or selective cyclooxygenase-2 (COX-2) inhibitor-type painkillers. If you are taking one of these, the doctor may want to check your kidney function when starting or adjusting treatment (see “Special warnings regarding use of the medicine”).
- Lithium, a medicine used to treat certain types of psychiatric disorders.
- Furosemide, a medicine belonging to the type known as diuretics, which are used to increase the amount of urine you produce.
- Nitroglycerin, a medicine to treat angina pectoris.

- Certain types of antibiotics (from the rifampicin group), cyclosporin (used to prevent rejection of transplanted organs) or antivirals such as ritonavir (used to treat HIV/AIDS).
- Metformin, a medicine used to treat diabetes.

If any of the above conditions apply to you, tell to the doctor or pharmacist before taking Sector.

Use of the medicine and food

Sector can be taken with or without food.

Pregnancy, breastfeeding and fertility

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

Pregnancy

You must tell your attending doctor if you are pregnant (or are planning to become pregnant).

Your doctor will usually recommend that you stop taking this medicine before you become pregnant or as soon as you find out you are pregnant, and will recommend that you take another medicine instead of **Sector**.

This medicine is not recommended in early pregnancy, and must not be taken when you are more than 3 months pregnant, as it may cause serious harm to the baby when taken after the third month of pregnancy.

Breastfeeding

Sector is not recommended for mothers who are breastfeeding. Tell the doctor if you are breastfeeding or will start breastfeeding.

Driving and operating machinery

Before you drive a car, use tools, operate machinery or carry out other activities that require concentration, make sure you know how **Sector** affects you. If you feel dizzy or very tired while taking the medicine, do not drive, ride a bicycle, use any tools or operate machinery.

Important information regarding some of the ingredients of the medicine

Sector contains less than 1 mmol (23 mg) sodium per dose and is considered to be essentially sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation. The dosage and the treatment regimen will be determined by the doctor only.

The usual starting dosage is generally one 50 mg or 100 mg tablet, twice a day (one tablet in the morning and one tablet in the evening).

The doctor will determine the exact starting dosage based on the medicines you took in the past and your blood pressure. After that, the doctor will adjust the dosage in accordance with your reaction to treatment every 2-4 weeks until a dosage optimal for you is identified.

The recommended target dosage is generally 200 mg, twice a day (one tablet in the morning and one tablet in the evening).

Let your doctor know if you have hyperkalemia (high blood potassium levels [more than 5.4 mmol/l]) or if your blood pressure is lower than 100 mmHg, as treatment should not be initiated under such conditions. If your blood pressure is above 100 mmHg but lower than 110 mmHg, your doctor will consider a starting dose of 50 mg, twice a day.

Elderly patients

If you are 75 years of age or older, your doctor will consider a starting dosage of 50 mg, twice daily.

Patients taking **Sector** may develop low blood pressure (dizziness, light-headedness), a high level of potassium in the blood (detectable in blood tests the doctor will perform) or decreased kidney function. If this happens, your doctor may reduce the dosage of any other medicine you are taking, temporarily reduce **Sector** dosage or stop **Sector** treatment entirely.

Do not exceed the recommended dose.

Swallow the medicine with a glass of water. **Sector** can be taken with or without food.

Sector 50 – to ease swallowing, the tablet can, if necessary, be divided, for immediate use only.

Sector 100 – the tablet can be halved for immediate use. There is no information regarding crushing or chewing.

Sector 200 – there is no information regarding crushing, halving or chewing.

If you accidentally took a higher dosage

If you took an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. If you experience severe dizziness and/or fainting, refer to a doctor as soon as possible and lie down.

If you forget to take the medicine

It is recommended to take the medicine at the same time each day. If you forgot to take this medicine at the scheduled time, do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time and consult the doctor.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting a doctor or pharmacist.

If you stop taking the medicine, your condition may worsen. Do not stop taking the medicine, unless the doctor has instructed you to do so.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Sector** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Some side effects may be serious.

Stop taking **Sector** and seek immediate medical attention if you notice swelling of the face, lips, tongue and/or throat, which may cause difficulties in breathing or swallowing. These symptoms may be signs of angioedema (an uncommon side effect which may affect up to 1 user in 100).

Additional side effects

If any of the side effects listed below become severe, tell the doctor or pharmacist.

Very common side effects (effects that occur in more than 1 user in 10):

- Low blood pressure which can cause symptoms of dizziness and lightheadedness.
- High levels of potassium in the blood, that show up in a blood test (hyperkalemia).
- Poor renal function (renal impairment).

Common side effects (effects that occur in 1-10 users in 100):

- Cough.
- Dizziness.
- Diarrhea.
- Low levels of red blood cells (that show up in a blood test (anemia)).
- Fatigue.
- (Acute) inability of the kidney to work properly (renal failure).
- Low levels of potassium in the blood that show up in a blood test (hypokalemia).
- Headache.
- Fainting.
- Weakness.
- Nausea.
- Low blood pressure (dizziness, lightheadedness) when switching from sitting or lying to standing position.
- Gastritis (stomach pain, nausea).
- Spinning sensation (vertigo)
- Low levels of sugar in the blood that show up in a blood test (hypoglycemia).

Uncommon side effects (effects that occur in 1-10 in 1,000 users):

- Allergic reaction with rash and itching (hypersensitivity).
- Dizziness when switching from sitting to standing position.
- Low levels of sodium in the blood, shown in a blood test (hyponatremia).

Rare side effects (effects that occur in 1-10 in 10,000 users):

- Seeing, hearing or feeling things that are not there (hallucinations).
- Changes in sleep patterns (sleep disorders).

Very rare side effects (effects that occur in less than 1 user in 10,000):

- Paranoia.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "[Report Side Effects of Drug Treatment](#)" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

Additionally, you can report to “[Unipharm Ltd.](#)”.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept 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 the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store below 25°C and in a place protected from light.
- Do not throw away any medicines via wastewater (sewer). Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

- In addition to the active ingredients, the medicine also contains:
Tablet core (Sector 50, 100, 200)
Microcrystalline cellulose, crospovidone, magnesium stearate, sodium lauryl sulfate, colloidal silicon dioxide.
Tablet coating (Sector 50, 200)
Hypromellose, titanium dioxide, polyethylene glycol, iron oxide yellow.
Tablet coating (Sector 100)
Hypromellose, titanium dioxide, polyethylene glycol.

What the medicine looks like and the contents of the package:

Sector 50 are film-coated, round, biconvex, yellow-orange tablets with a break line on one side of the tablet.

Sector 100 are film-coated, round, biconvex, white tablets with a break line on one side of the tablet.

Sector 200 are film-coated, oblong, biconvex, yellow-orange tablets.

The tablets are packaged in blisters (trays) inserted into a carton package.

Sector 50 are available in package sizes of 28, 30, 56 or 60 tablets.

Sector 100 are available in package sizes of 28 or 56 tablets.

Sector 200 are available in a package size of 56 tablets.

Not all package sizes may be marketed.

Registration holder and address: Unipharm Ltd., P.O. Box 21429, Tel Aviv, 6121301.

Manufacturer and address: Unipharm Ltd., “Mevo Carmel” Industrial Park.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Sector 50: 171 71 37432 99

Sector 100: 171 72 37119 99

Sector 200: 171 73 37120 99

Revised in February 2024 according to MOH guidelines.

09B23

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