

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

**STATOR 5
STATOR 10
STATOR 20
STATOR 40**

Film-coated tablets

Composition:

Each **Stator 5** tablet contains:
Rosuvastatin (as calcium salt) 5 mg
Each **Stator 10** tablet contains:
Rosuvastatin (as calcium salt) 10 mg
Each **Stator 20** tablet contains:
Rosuvastatin (as calcium salt) 20 mg
Each **Stator 40** tablet contains:
Rosuvastatin (as calcium salt) 40 mg

For inactive and allergenic ingredients in the preparation, please see section 2 – “Important information about 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 for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

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

1. WHAT IS THE MEDICINE INTENDED FOR?

Stator is indicated for lowering high blood cholesterol and triglyceride levels when dietary changes and exercise fail to do so. During treatment with **Stator**, continue with the cholesterol-reducing diet and physical activity.

High blood cholesterol levels may increase the risk of heart attack or stroke.

Therapeutic group

An inhibitor of the HMG-CoA reductase enzyme.

Stator belongs to a group of medicines called statins and acts by lowering blood fat level. The most common one is called cholesterol. There are several types of cholesterol in the blood: “bad cholesterol” and “good cholesterol”. **Stator** acts by assisting the body in blocking production of “bad cholesterol” and in clearing it from the body and helps to increase the “good cholesterol” levels.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive to the active ingredient or to any of the additional ingredients contained in the medicine (see section 2 – “Important information about some of the ingredients of the medicine” and section 6 – “Further information”).
- You are pregnant or breastfeeding. If you become pregnant while using **Stator**, stop taking **Stator** immediately and inform your doctor. Avoid becoming pregnant by using appropriate contraceptive measures.
- You have a liver disease.
- You are suffering from severe kidney problems.
- You are suffering from repeated or unexplained muscle aches or pains.
- You are taking a drug combination of sofosbuvir/velpatasvir/voxilaprevir (used for the treatment of a viral infection of the liver called hepatitis C).

- You are taking cyclosporin (for example, following an organ transplant).
 - You are under the age of 18.
- If any of the above apply to you (or you are in doubt), please refer to your doctor.
- In addition, do not use the 40 mg tablets (the highest dosage) if:**
- You have moderate kidney function problems (if in doubt, please refer to a doctor).
 - You have thyroid function problems.
 - You have repeated or unexplained muscle aches or pains, if you have a family or personal history of muscle problems, or if you have had muscle problems in the past while taking other cholesterol-lowering medicines.
 - You regularly consume large amounts of alcohol.
 - You are of Asian origin (Chinese, Filipino, Indian, Korean, Vietnamese, Japanese).
 - You take cholesterol-lowering medicines known as fibrates.
- If any of the above apply to you (or you are in doubt), please refer to your doctor.

Special warnings regarding use of Stator

Before treatment with Stator, tell the doctor if:

- You regularly consume large amounts of alcohol.
- You have impaired liver, kidney or thyroid function.
- You take other cholesterol-lowering medicines known as fibrates. Please read this leaflet carefully even if you have used medicines to reduce cholesterol in the past.
- You are taking medicines to treat the human immunodeficiency virus (HIV), such as: ritonavir with lopinavir and/or atazanavir. Please refer to section “Drug interactions”.
- You are taking, or have taken in the last 7 days, antibiotics containing fusidic acid (to treat bacterial infection, orally or by injection). The combination of fusidic acid and **Stator** can lead to serious muscle problems (rhabdomyolysis). Please refer to section “Drug interactions”.
- You have severe respiratory failure.
- You have repeated or unexplained muscle aches or pains, or if you or a family member have had muscle problems, or if you have a history of muscle problems when taking cholesterol-lowering preparations. Inform the attending doctor immediately if you experience unexplained muscle aches or pains, especially if these are accompanied by malaise or fever. Also, inform the doctor if you have persistent muscle weakness.

If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking **Stator** or other related medicines.

- You are of Asian origin (Chinese, Filipino, Indian, Korean, Vietnamese, Japanese). The doctor will choose the right starting dose of **Stator** to suit you.
- You are over the age of 70 (the doctor will choose the right starting dose of **Stator** to suit you).

If any of the above-listed conditions apply to you (or if you are uncertain):

Do not take **Stator** 40 mg (the highest dosage) and check with your doctor or pharmacist before starting to use any dosage of **Stator**. Serious skin reactions including Stevens-Johnson syndrome and drug reaction with eosinophilia and systemic symptoms syndrome (DRESS) have been reported in association with **Stator** treatment. Stop using **Stator** and seek medical attention immediately if you notice any of the symptoms described in section 4 – “Side effects”.

In a small number of patients, statins may affect the liver; this is identified by a simple blood test that checks for an increase in liver enzyme levels. Therefore, the doctor will ask you to perform blood tests of liver function, before and during treatment with **Stator**. While you are being treated with this medicine, your doctor will

monitor you closely if you have diabetes, or are at risk of developing diabetes. You may be at risk of developing diabetes if you have high levels of sugars and fats in your blood, or if you are overweight and have high blood pressure.

Children and adolescents

Stator is not intended for children and adolescents below 18 years of age.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, if you are taking:

- Warfarin, clopidogrel, ticagrelor (or any other drug used for thinning the blood).
- Cyclosporin (used following organ transplant).
- Fibrates (such as gemfibrozil or fenofibrate) or any other cholesterol-lowering medicine (such as ezetimibe).
- Indigestion medicines (used as antacids in the stomach).
- Erythromycin (an antibiotic), fusidic acid (an antibiotic – see below and in section “Special warnings regarding use of **Stator**”).
- Oral contraceptives.
- Regorafenib (to treat cancer).
- Darolutamide (to treat cancer).
- Capmatinib (to treat cancer).
- Hormone replacement therapy.
- Fostamatinib (to treat low platelet counts).
- Febuxostat (to treat and prevent high blood levels of uric acid).
- Teriflunomide (to treat multiple sclerosis).
- Medicines to treat viral infections, including the human immunodeficiency virus (HIV) or hepatitis C, alone or in combination with (please see section “Special warnings regarding use of **Stator**”): ritonavir, lopinavir, atazanavir, sofosbuvir, voxilaprevir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir. The effect of these medicines could be changed by concomitantly use with **Stator** or they could change the effect of **Stator**.
- Fusidic acid (an antibiotic) – If you need to take oral fusidic acid to treat a bacterial infection, you will temporarily need to stop treatment with **Stator**. The doctor will tell you when you can start taking the medicine again. Taking **Stator** with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4 – “Side effects”.

Use of the medicine and food

Stator can be taken regardless of food.

Pregnancy, breastfeeding and fertility

Do not take **Stator** if you are pregnant or breastfeeding. If you become pregnant while using **Stator**, stop taking **Stator** immediately and inform your doctor. Avoid becoming pregnant by using appropriate contraceptive measures during the course of treatment with this medicine.

Driving and operating machinery

Most patients can drive a car and operate machinery when using **Stator** – the medicine will not affect your capacity to perform these activities. However, some patients may feel dizzy while using **Stator**. If you feel dizzy, refer to a doctor before operating machinery or driving a car.

Important information about some of the ingredients of the medicine

The medicine contains lactose.

If you have been told by the doctor that you have an intolerance to some sugars (lactose or milk sugars), consult the doctor before taking this medicine. Please see section 6 – “Further information”. Each **Stator 5** tablet contains 14.5 mg lactose. Each **Stator 10** tablet contains 29 mg lactose.

Each **Stator 20** tablet contains 58 mg lactose.

Each **Stator 40** tablet contains 116 mg lactose.

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 treatment regimen will be determined by the doctor only.

The usual dosage is generally:

Treatment with **Stator** will begin with one 5 mg or 10 mg tablet once a day, even if you have previously taken other statins in higher dosages.

The choice of your start dose will depend upon:

- Your cholesterol level.
 - The level of risk you have of experiencing a heart attack or stroke.
 - The likelihood that you will be more sensitive to a possible side effect.
- Your doctor may decide to give you the lowest dose, 5 mg, if:
- You are of Asian origin (Chinese, Filipino, Indian, Korean, Vietnamese, Japanese).
 - You are over 70 years of age.
 - You have a moderate kidney function problem.
 - You are at risk of suffering from muscle pains (myopathy).

Increasing the dose and maximum daily dose

Your doctor may decide to increase the dose you are taking, so that it will be right for you. If you started with the **Stator 5** mg dose, the doctor may double the dose to **Stator 10** mg, and then to 20 mg and then, if necessary, will increase it to 40 mg. If you started on a dose of **Stator 10** mg, the doctor may double the dose to 20 mg and then, if necessary, will increase it to 40 mg. There will be a gap of 4 weeks between every dose increase. The maximum daily dose is 40 mg and is usually given to patients with very high levels of cholesterol and a high risk of heart attack or stroke whose cholesterol levels are not lowered enough with 20 mg.

Do not exceed the recommended dose.

If aluminum or magnesium salt-type antacids are being taken, take **Stator** at least two hours before taking the aluminum/magnesium salt antacid.

Regularly check cholesterol levels to confirm that your cholesterol has reached and is maintained at the desired level.

The medicine can be taken at any time of day, with or without food. It is recommended to take the medicine at the same time every day. Swallow the tablets whole with water.

Do not halve **Stator 5**! If necessary, **Stator 10**, **Stator 20** and **Stator 40** can be halved for immediate use.

There is no information regarding crushing or chewing the tablet. **If you accidentally take too high a dose**, contact your doctor or refer to a hospital emergency room.

If you take an overdose or if a child has accidentally swallowed the medicine, refer to a doctor immediately or proceed to a hospital emergency room, and bring the package of the medicine with you. **If you forgot to take the medicine**, skip the forgotten dose and take the next dose according to the regular schedule.

Never take two doses together to compensate for a forgotten dose. Adhere to treatment as recommended by your doctor. Even if there is an improvement in your health, do not stop taking the medicine without consulting with the doctor.

If you stop treatment with the medicine, your cholesterol levels might increase again.

Do not take medicines in the dark! Check the label and the 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 **Stator** may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Effects requiring special attention; stop treatment with Stator and refer to a doctor immediately if:

- You have one of the following allergic reactions:
 - Breathing difficulty with or without swelling of the face, lips, tongue and/or throat.
 - Swelling of the face, lips, tongue and/or throat, which can cause swallowing difficulties.
 - Severe skin itching (with raised blisters).
 - Reddish, non-elevated, target-like or circular patches on the body, sometimes with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome). Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- You have unusual muscle aches and pains, which go on for longer than you might expect. As with other statins, a small number of patients have experienced an unpleasant muscle effect and, rarely, this effect can become life-threatening, damaging muscles – a condition known as rhabdomyolysis.
- You experience muscle tear.
- You have lupus-like disease syndrome (including rash, joint disorders and effect on blood cells).

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

- Constipation
- Headaches
- Malaise
- Dizziness
- Abdominal pain
- Weakness
- Muscle pain
- Increase in the amount of protein in the urine – this usually returns to normal without having to stop taking the preparation (only for **Stator 40** mg).
- Diabetes – the risk of developing diabetes is higher if you have high levels of fats and sugar in the blood, are overweight, and have high blood pressure. You must be under medical supervision during the course of treatment.

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

- Skin rash, itching and other skin reactions.
- Increase in the amount of protein in the urine – this usually returns to normal without having to stop taking the preparation (only for **Stator 5** mg, 10 mg and 20 mg).

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

- Severe allergic reaction whose signs include: swelling of the face, lips, tongue and/or throat, difficulty swallowing and breathing, severe itching of the skin (with raised blisters). If you think you have an allergic reaction, stop taking **Stator** and seek medical help immediately.
- Muscle damage in adults – as a precaution, stop taking **Stator** and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than expected.
- Severe abdominal pain (inflamed pancreas).
- Increase in liver enzymes in the blood.
- Bleeding or bruising more easily than normal due to low levels of blood platelets.
- Lupus-like disease syndrome (including rash, joint disorders and effect on blood cells).

Very rare side effects (effects that occur in less than one in 10,000 patients):

- Jaundice (yellowing of the skin and eyes).
- Hepatitis (liver inflammation).
- Traces of blood in the urine.
- Joint pains

- Nerve damage in the arms and legs (e.g., numbness or tingling sensation).
- Memory loss.
- Breast enlargement in men (gynecomastia).

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- Diarrhea
- Edema (swelling as a result of fluid buildup).
- Sleep disturbance, including insomnia and nightmares.
- Problems with sexual function.
- Depression
- Shortness of breath
- Breathing problems including a persistent cough and/or shortness of breath or fever.
- Permanent muscle weakness.
- Cough
- Tendon injury.

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?

- Store below 25°C and in a place protected from light.
- Avoid poisoning! This medicine, and any other medicine, must 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.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains: Microcrystalline cellulose, Lactose anhydrous, Magnesium oxide, Croscarmellose sodium, Magnesium stearate, Opadry white, Opadry brown, Opadry yellow.

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

Stator is packaged in trays (blisters) that are inserted into a carton package. **Stator** is available in package sizes of 7, 10, 14, 21, 28, 30 tablets. Not all package sizes may be marketed.

Stator 5 are round, beige, biconvex, film-coated tablets.

Stator 10 are round, beige, biconvex, film-coated tablets, with a break line on one side.

Stator 20 are round, beige, biconvex, film-coated tablets, with a break line on one side.

Stator 40 are oblong, beige, biconvex, film-coated tablets, with a break line on one side.

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

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

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

Stator 5: 143 12 33069 02

Stator 10: 143 13 31932 02

Stator 20: 143 14 31933 02

Stator 40: 143 15 31934 02

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