

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS

(PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Simvastatin Teva 10 mg Simvastatin Teva 20 mg Simvastatin Teva 40 mg Simvastatin Teva 80 mg

Tablets

Composition:

Each tablet of Simvastatin Teva 10 mg contains:

Simvastatin 10 mg

Each tablet of Simvastatin Teva 20 mg contains:

Simvastatin 20 mg

Each tablet of Simvastatin Teva 40 mg contains:

Simvastatin 40 mg

Each tablet of Simvastatin Teva 80 mg contains:

Simvastatin 80 mg

For information regarding inactive ingredients and allergens in the preparation see section 6 - "Additional information" and section 2 - "Important information about some ingredients of the medicine".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

Do not use in children and adolescents under the age of 20.

1. WHAT IS THE MEDICINE INTENDED FOR?

In patients with coronary heart disease and hypercholesterolemia, Simvastatin Teva reduces:

- The overall mortality risk by lowering mortality from heart disease.
- The risk of a non-fatal heart attack.
- The risk of invasive procedures to restore blood flow to the heart (such as balloon dilation or bypass surgery).
- The risk of stroke and Transient Ischemic Attack - TIA.

Simvastatin Teva is indicated for lowering the levels of LDL and other fatty substances in the blood and raising HDL blood levels in patients with hyperlipidemia (high level of fats in the blood).

Therapeutic class: Statins, HMG-CoA reductase enzyme inhibitors.

How does Simvastatin Teva work:

Simvastatin Teva contains the active ingredient simvastatin. Simvastatin Teva is used to lower blood levels of total cholesterol, levels of the "bad" cholesterol (LDL cholesterol), and the levels of fatty compounds called triglycerides. In addition, Simvastatin Teva raises the levels of the "good" cholesterol (HDL cholesterol). Cholesterol is one of the fatty components found in the blood. The total cholesterol is made up mainly of LDL and HDL cholesterol. LDL cholesterol is often called the "bad" cholesterol, because it may build up on the walls of the arteries and form plaque. With time plaque buildup may cause narrowing of the arteries. This narrowing may slow or block blood flow to vital organs such as the heart or brain. Blocking of the blood flow may lead to a heart attack or stroke. HDL cholesterol is often called the "good" cholesterol, because it helps prevent plaque buildup in the arteries and prevents heart disease. Triglycerides are another type of fat found in the blood that may increase the risk of heart disease.

You need to stick to a low cholesterol diet while taking this medicine.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any one of the other ingredients the medicine contains (see section 6 - "Additional information" and section 2 - "Important information about some ingredients of the medicine").
- You currently suffer from liver problems.
- You are pregnant or breastfeeding.
- You are taking medicines that contain one or more of the following active ingredients:
 - Itraconazole, ketoconazole, posaconazole or voriconazole (used to treat fungal infections).
 - Erythromycin, clarithromycin or telithromycin (used to treat infections).
 - HIV protease inhibitors such as indinavir, nelfinavir, ritonavir and saquinavir (HIV protease inhibitors are used to treat HIV infections).
 - Boceprevir or telaprevir (used to treat hepatitis C infection).
 - Nefazodone (used to treat depression).
 - Cobicistat.
 - Gemfibrozil (used to lower cholesterol).
 - Ciclosporin (used in patients after organ transplant).
 - Danazol (artificial hormone used to treat endometriosis, a condition in which parts of the endometrial tissue grow outside the uterus).
- Do not take more than 40 mg of Simvastatin Teva if you are taking lomitapide (a medicine used to treat a severe and rare medical condition of genetic cholesterol).

Ask the doctor if you are not sure if your medicine is listed above.

Special warnings regarding the use of the medicine:

Before treatment with Simvastatin Teva, tell the doctor:

- About all your medical problems including allergies.
- If you consume large amounts of alcohol.
- If you have suffered in the past from liver disease. Simvastatin Teva treatment may not be right for you.
- If you are about to undergo surgery. You may need to stop taking Simvastatin Teva for a short time.
- If you suffer from severe respiratory failure.
- If you are of Asian descent. You may need a different dosage.
- If you are taking or have taken in the last 7 days a medicine called fusidic acid (a medicine used to treat a bacterial infection) orally or by injection. Concomitant use of fusidic acid with Simvastatin Teva may lead to severe muscle problems (rhabdomyolysis).
- If you suffer or have suffered in the past from myasthenia (a disease characterized by general muscle weakness, sometimes including muscles involved in respiration) or ocular myasthenia (a disease that causes weakness of the eye muscles), since statins may sometimes worsen the disease or lead to its occurrence (see section 4).

Contact your doctor immediately if you experience an unexplained muscle pain, tenderness or muscle weakness.

This is because in rare cases, muscle problems may be severe, including muscle breakdown resulting in kidney damage, and in very rare cases death. The risk of muscle breakdown is higher in patients taking high doses of Simvastatin Teva, particularly an 80 mg dosage. In addition, the risk of muscle breakdown is higher in certain patients. Talk to your doctor if any of the following applies to you:

- You consume large amounts of alcohol.
- You have kidney problems.
- You have thyroid problems.
- You are 65 years old or older.
- You are female.
- You had muscle problems in the past during treatment with cholesterol-lowering medicines called "statins" or fibrates.
- You or a family member has a hereditary muscle disease.

Furthermore, tell the doctor or pharmacist if you have constant muscle weakness.

Additional tests and medicines may be required to diagnose and treat this.

Tests and follow-up:

The doctor will refer you to a blood test before you start using this medicine and if you have any symptoms of liver problems during the treatment period with this medicine. This is to test your liver function. After starting treatment with Simvastatin Teva, you may be referred by your doctor to a liver function blood test.

Your doctor will monitor you closely, if you have diabetes or you are at risk of developing diabetes. You are at risk of developing diabetes if you have high levels of sugars and fats in your blood, excess weight and high blood pressure.

Drug interactions:

If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the doctor or pharmacist. Taking Simvastatin Teva with one of the medicines listed below may increase the risk of muscle problems (some are mentioned in section 2 - "Do not use this medicine if").

- **If you need to take fusidic acid orally to treat a bacterial infection, you will need to temporarily stop taking Simvastatin Teva. Your doctor will instruct you when you can start taking Simvastatin Teva safely again. Taking Simvastatin Teva concomitantly with fusidic acid may rarely cause muscle weakness, muscle tenderness or muscle pain (rhabdomyolysis). For more information about rhabdomyolysis see section 4 - "Side effects".**
- Ciclosporin (often given to patients after organ transplant).
- Danazol (artificial hormone used to treat endometriosis, a condition in which parts of the endometrial tissue grow outside the uterus).
- Medicines with active ingredients such as itraconazole, ketoconazole, fluconazole, posaconazole or voriconazole (used to treat fungal infections).
- Fibrates with active ingredients such as gemfibrozil or bezafibrate (used to lower cholesterol).
- Erythromycin, clarithromycin, telithromycin (used to treat bacterial infections).
- HIV protease inhibitors such as indinavir, nelfinavir, ritonavir or saquinavir (used to treat HIV).
- Antiviral medicines for the treatment of hepatitis C such as boceprevir, telaprevir, elbasvir or grazoprevir (used to treat hepatitis C viral infection).
- Nefazodone (used to treat depression).
- Medicines containing the active ingredient cobicistat.
- Amiodarone (used to treat irregular heartbeat).
- Verapamil, diltiazem or amlodipine (used to treat high blood pressure, chest pain attributed to heart disease or other heart conditions).
- Lomitapide (a medicine used to treat a severe and rare medical condition of genetic cholesterol).
- Daptomycin (a medicine used to treat complicated infections of the skin and skin tissues and bacteremia). It is possible that the side effects affecting the muscles will be stronger when taking this medicine during treatment with Simvastatin Teva. The doctor may decide that you should stop taking Simvastatin Teva temporarily.
- Colchicine (used to treat gout).
- Ticagrelor (an anticoagulant).

In addition to the medicines listed above, tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription medicines. In particular, tell your doctor if you are taking one of the following medicines:

- Medicines with an active ingredient to prevent blood clotting, such as warfarin, phenprocoumon or acenocoumarol (anticoagulants)
 - Fenofibrate (also used to lower cholesterol)
 - Niacin (also used to lower cholesterol)
 - Rifampicin (used to treat tuberculosis)
- Tell all doctors prescribing a new medicine for you that you are taking Simvastatin Teva.

Use of the medicine and food:

Grapefruit juice contains one or more compounds that affect the way in which the body breaks down certain medicines, including Simvastatin Teva. **Consuming grapefruit juice should be avoided.**

Pregnancy and breastfeeding:

Do not use Simvastatin Teva if you are pregnant, trying to become pregnant or think you might be pregnant. If you become pregnant during treatment with Simvastatin Teva, stop taking it and contact your doctor immediately.

Do not take Simvastatin Teva if you are breastfeeding, as it is not known if the medicine passes into breast milk. Consult the doctor or pharmacist before starting treatment with any medicine.

Driving and operating machinery:

Simvastatin Teva is not expected to affect your ability to drive or operate machinery. However, it should be taken into account that some people may feel dizzy after taking Simvastatin Teva.

Important information about some ingredients of the medicine:

Simvastatin Teva contains a sugar called **lactose**. If you have been told by the doctor that you have an intolerance to certain sugars, contact the doctor before taking this medicine.

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 how to use the preparation.

The dosage and treatment regimen will be determined only by the doctor. The generally accepted dosage is:

The recommended initial dosage is 10 mg or 20 mg once daily, in the evening, with or without food.

How to take the medicine:

The tablet should be swallowed with some water.

The tablet can be halved on the score-line. There is no information regarding pulverization and chewing.

Because of the increased risk of muscle problems, the dosage of 80 mg is only for patients who are taking an 80 mg dosage on a permanent basis (12 months or more) without muscle damage and who do not need to take certain other medicines concomitantly with Simvastatin Teva which may increase your risk for developing muscle damage.

Your doctor may prescribe you lower dosages, especially if you are taking certain of the above mentioned medicines or if you have certain medical problems. If you are also taking bile acid sequestrant medicines (cholesterol lowering medicines) such as cholestyramine, you need to take Simvastatin Teva at least two hours before or four hours after taking these medicines. **Do not exceed the recommended dose. If you accidentally took a higher dose or if a child accidentally swallowed the medicine, immediately proceed to a hospital emergency room and bring the package of the medicine with you.**

If you forgot to take the medicine, do not take a double dose. Take the next dose at the scheduled time and consult a doctor. You should follow the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting your doctor. **If you stop taking the medicine** Continue taking Simvastatin Teva unless your doctor tells you to stop. If you stop taking Simvastatin Teva, your cholesterol may rise again.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them. If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, using Simvastatin

Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Rare and serious side effects - side effects that occur in 1-10 out of 10,000 users:

Stop using this medicine and refer immediately to a doctor or to an emergency room if you experience one of the following side effects:

- Muscle pain, muscle tenderness, muscle weakness, muscle cramps or muscle rupture (very rare). In rare cases these muscle problems may be severe, including muscle breakdown resulting in kidney damage, and in very rare cases even death.
- Hypersensitivity (allergic) reactions including: swelling of the face, tongue, or throat that may cause difficulty breathing (angioedema).
- Severe muscle pain, usually in the shoulders or hips (polymyalgia rheumatica).
- Rash with weakness in the limbs and the neck muscles.
- Rash that may appear on the skin and sores in the mouth (lichenoid drug eruptions) (very rare).
- Pain or inflammation in the joints.
- Inflammation of blood vessels (vasculitis).
- Unusual bruising, rash and swelling of the skin (dermatomyositis), hives, skin sensitivity to the sun, fever, flushing.
- Shortness of breath (dyspnea) and generally feeling unwell.
- A condition similar to lupus (which includes a rash, joint problems and an effect on blood cells).
- Inflammation of the liver accompanied by the following symptoms: yellowing of the skin and the eyes, itching, dark-colored urine or light-colored feces, feeling tired or weak, loss of appetite; fatal and non-fatal liver failure (very rare).
- Inflammation of the pancreas usually accompanied by severe abdominal pain.

Very rare serious side effects - effects that occur in less than one out of 10,000 users:

- Severe allergic reaction that causes breathing difficulties or dizziness (anaphylaxis).
- Gynecomastia (breast enlargement in men).

Rare side effects - side effects that occur in 1-10 out of 10,000 users:

- Low red blood cell count (anemia).
- Numbness or weakness of the hands and feet.
- Headache, tingling sensation, dizziness.
- Blurred vision, impaired vision.
- Digestive system disturbances (abdominal pain, constipation, swelling, digestive difficulties, diarrhea, nausea, vomiting).
- Rash, itching, hair loss.
- Weakness.
- Sleeping problems (very rare).
- Poor memory (very rare), memory loss, confusion.

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

- Erectile dysfunction.
- Depression.
- Tendon problems, sometimes with complications to the extent of rupturing of the tendon.
- Constant muscle weakness.
- Myasthenia gravis (a disease that leads to general muscle weakness and in certain cases also to weakness of the muscles involved in respiration).
- Ocular myasthenia (a disease that causes weakness of the eye muscles).

Talk to the doctor if you feel weakness in the arms or legs which worsens after a period of activity, double vision or drooping eyelids, difficulty swallowing, or shortness of breath.

Possible side effects when using statins:

- Sleep disturbances including nightmares.
- Difficulties in sexual functioning.
- Breathing problems including persistent cough and / or shortness of breath or fever.
- Diabetes. This is more likely if you have high levels of sugars and fats in your blood, excess weight and high blood pressure. Your doctor will monitor you during the course of treatment with this medicine.

Laboratory values results:

Elevations in certain laboratory blood tests of liver function and the muscle enzyme (creatine kinase) have been observed.

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

Reporting side effects:

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Storage:

Store this medicine in a dry and dark place, below 25°C.

6. ADDITIONAL INFORMATION

In addition to the active ingredient the medicine also contains:

Lactose monohydrate, pregelatinized starch, microcrystalline cellulose, ascorbic acid, citric acid monohydrate, magnesium stearate, butylhydroxyanisole, hypromellose, titanium dioxide, macrogol, triacetin, red iron oxide, 10 mg, 20 mg, 80 mg; yellow iron oxide, 80 mg; black iron oxide.

What does the medicine look like and what are the contents of the package:

Simvastatin Teva 10 mg:

A light pink, oval-shaped, film coated tablet, on one side of the tablet there is a score-line and the other side is plain.

Quantity in the package: 30 tablets.

Simvastatin Teva 20 mg:

A tan, oval-shaped, film coated tablet, on one side of the tablet there is a score-line and the other side is plain.

Quantity in the package: 30 tablets.

Simvastatin Teva 40 mg:

A pink, oval-shaped, film coated tablet, on one side of the tablet there is a score-line and the other side is plain.

Quantity in the package: 10, 30, 60, 100 tablets.

Simvastatin Teva 80 mg:

A brick red, oval-shaped, film coated tablet, on one side of the tablet there is a score-line and the other side is plain.

Quantity in the package: 12, 30 tablets.

Name and address of the license holder and manufacturer:

Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020.

Revised in January 2024.

Registration number of the medicine in the national drug registry of the Ministry of Health:

Simvastatin Teva 10 mg: 120.94.30070

Simvastatin Teva 20 mg: 129.75.30071

Simvastatin Teva 40 mg: 120.18.30737

Simvastatin Teva 80 mg: 128.05.30671

SIMVASTATIN TABS PIL MW0124

teva