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

The medicine is dispensed with a doctor's prescription only

Atorvastatin Teva® 10 mg
Tablets

The active ingredient and its quantity:
Each tablet contains:
Atorvastatin 10 mg (as calcium)

Atorvastatin Teva® 20 mg
Tablets

The active ingredient and its quantity:
Each tablet contains:
Atorvastatin 20 mg (as calcium)

Atorvastatin Teva® 40 mg
Tablets

The active ingredient and its quantity:
Each tablet contains:
Atorvastatin 40 mg (as calcium)

Atorvastatin Teva® 80 mg
Tablets

The active ingredient and its quantity:
Each tablet contains:
Atorvastatin 80 mg (as calcium)

For the list of inactive ingredients, please see section 6.

Read this 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 your treatment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar to yours.
This medicine is not usually intended for children under the age of 10.
Be sure to maintain a low-cholesterol diet and to perform physical activity in addition to use of this medicine.

1. WHAT IS THE MEDICINE INTENDED FOR?

- The medicine is intended to reduce blood lipid levels (cholesterol and triglycerides) and to increase HDL.
- To prevent heart and vascular diseases (such as heart attack and stroke) in patients at high risk for a primary event.
- In patients with coronary heart disease, the medicine reduces the risk of myocardial infarction, stroke, hospitalization due to heart failure, angina pectoris and/or need for catheterization.

Therapeutic group:
Statins - HMG-CoA reductase enzyme inhibitors.

2. BEFORE USING THE MEDICINE:

☒ Do not use the medicine if:
- you are pregnant, intend to become pregnant, are breastfeeding or intend to breastfeed.
- you are a woman of child-bearing age and are not using appropriate contraceptive methods.
- you are sensitive to atorvastatin, similar medicines used to lower blood lipid levels or to the inactive ingredients of the preparation.
- Do not use this medicine in case of an active liver disease or if you have a persistent elevation of blood transaminase (liver enzymes) levels.
- you are suffering from a disease of the skeletal muscles.
- Do not use the medicine in children below 10 years of age and in girls who have not yet started menstruating.
- you are taking cyclosporine, telaprevir (for the treatment of hepatitis C), or a combination of tipranavir and ritonavir (for the treatment of the AIDS virus).

Special warnings regarding use of the medicine:
- The preparation contains sodium and lactose and may cause allergy in people sensitive to either of these substances.
- During the course of treatment with this medicine, it is recommended to visit a doctor regularly.
- Refer to a doctor immediately if you think you are pregnant.
- Before surgery (including dental surgery) or an emergency procedure, inform the doctor that you are taking this medicine.
- Women of child-bearing age must use appropriate contraceptive methods.
- Refer to a doctor immediately if muscle pain, tenderness or weakness occur, especially if these effects are accompanied by unusual fatigue or fever.
- Concomitant administration of atorvastatin with fibric acid derivatives, erythromycin, clarithromycin, protease inhibitors to treat AIDS, niacin, ezetimibe, fusidic acid, azole antifungals or colchicine may increase the risk of muscle damage (see section 4 – "Side Effects" in the leaflet). Regarding fusidic acid, the doctor must consider temporary discontinuation of treatment with Atorvastatin Teva.
- Statins may increase the risk of onset of diabetes in patients who are in a risk group; blood sugar levels must be monitored in these patients. If you are at increased risk of developing diabetes (borderline blood sugar levels, significant overweight, high blood lipid levels or high blood pressure), monitoring by a doctor and periodic blood tests are necessary during the course of treatment with the medicine.
- Do not drink more than one or two small cups of grapefruit juice per day, as consumption of large quantities of grapefruit may affect the activity of the medicine.
- If you are sensitive to any food or medicine, inform the doctor before taking the medicine.

! Before treatment with Atorvastatin Teva, tell the doctor if:
- if you are over the age of 70.
- if you are suffering, or have suffered in the past, from impaired function of the liver, kidney/ urinary system, thyroid, serious problems in the respiratory system.
- if you consume a lot of alcohol or if you used to drink large quantities of alcohol in the past.
- if you recently experienced a stroke or a transient ischemic attack or you are suffering, or have suffered, from cerebral hemorrhaging.
- if you have suffered from recurrent or unexplained muscle aches, or if you or your family members are suffering from a muscle disorder or if you suffered from muscle problems during the course of treatment with other medicines used for lowering blood lipids.
- if you are suffering from seizures, a disorder or deficiency in electrolytes or metabolic enzymes, a severe infection, hypotension, diabetes or if you recently underwent surgery or trauma.

! Tests that should be performed before using the medicine:
- Before starting treatment with this medicine, a liver function test should be performed.

! If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:
- Medicines that in combination with atorvastatin increase its blood concentration and may increase the risk of muscle pain: antibiotics such as: erythromycin, clarithromycin, fusidic acid, other cholesterol-lowering preparations (e.g., fibric acid derivatives, nicotinic acid), antifungal preparations from the azole group (e.g., ketoconazole, itraconazole), boceprevir (for treatment of hepatitis C), colchicine (for gout), medicines for the AIDS virus (protease inhibitors) such as: saquinavir, ritonavir, darunavir, fosamprenavir, lopinavir and nelfinavir, indinavir.
- Medicines that in combination with atorvastatin increase its blood concentration: diltiazem (for the heart and blood vessels), rifampicin (antibiotic) (concomitantly taken with atorvastatin), amlodipine (to treat hypertension).
- Medicines that in combination with atorvastatin decrease its blood concentration: efavirenz (e.g., Stocrin), rifampicin (antibiotic) (not administered in proximity to atorvastatin), antacids (containing magnesium or aluminum).
- Medicines whose blood concentrations rise when given in combination with atorvastatin: oral contraceptives containing norethindrone and ethinylestradiol, digoxin (for the heart) - you should be monitored.
- If you are taking anticoagulants (warfarin) - coagulation parameters should be monitored.
- Do not take Atorvastatin Teva together with the following medicines: cyclosporine, telaprevir (for treatment of hepatitis C), or a combination of tipranavir and ritonavir (for treatment of the AIDS virus).
- Additional interactions with Atorvastatin Teva:
- Medicines that affect the heart rate (e.g., amiodarone)
- Other preparations for regulation of blood lipid levels (e.g., colestipol, ezetimibe, gemfibrozil)
- Calcium channel blockers used to treat hypertension and angina pectoris (e.g., verapamil)
- St. John's wort (*Hypericum perforatum*), nefazodone (antidepressant)
- Medicines for epilepsy (e.g., phenytoin)
- Cimetidine (to inhibit secretion of gastric acids)
- Phenazone, corticosteroids.

! Use of the medicine and food:
Swallow the tablet whole with a little water.
The medicine can be taken with or without food.
Be sure to maintain a low-cholesterol diet during the course of treatment with this medicine.
Do not drink more than one or two small cups of grapefruit juice per day, as consumption of large quantities of grapefruit may affect the activity of the medicine.

! Use of the medicine and alcohol consumption:
Do not drink a lot of alcohol - do not drink large quantities of wine or alcoholic beverages during the course of treatment with the medicine (see section 2 - subsection "Before treatment with Atorvastatin Teva, tell the doctor if").

! Pregnancy and breastfeeding:
Do not use this medicine if you are pregnant, intend to become pregnant, are breastfeeding or intend to breastfeed.
Do not use this medicine if you are of child-bearing age unless you use appropriate contraceptive methods.
Refer to a doctor immediately if you think you are pregnant.

! Important information regarding some of the ingredients of the medicine:
- Regarding Atorvastatin Teva 10 mg: Each tablet contains 60.84 mg lactose.
- Regarding Atorvastatin Teva 20 mg: Each tablet contains 121.68 mg lactose.
- Regarding Atorvastatin Teva 40 mg: Each tablet contains 243.36 mg lactose.
- Regarding Atorvastatin Teva 80 mg: Each tablet contains 486.74 mg lactose.

3. HOW SHOULD YOU USE THE MEDICINE?

- Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.
- Do not chew! Swallow the tablet whole with a little water.
- Do not crush/halve/chew the tablet since it is coated.
- Wait at least two hours between taking this medicine and taking antacids.
- **Attention** - the bottle contains an oxygen absorber and a desiccant (plastic rolls). Do not swallow! Leave the oxygen absorber and desiccant in the bottle and close the bottle tightly after each use.

The dosage and treatment regimen will be determined by the doctor only.
Use this medicine at specified time intervals, as determined by the attending doctor.
Complete and adhere to the treatment as recommended by the doctor.
Before starting treatment, the doctor will instruct you about a low-cholesterol diet, which you should maintain also during the course of treatment with the medicine.

Tests and follow-up
- Before starting treatment with the medicine, the doctor will refer you for a liver function test.
- During the course of treatment with this medicine, the following tests should be performed: liver function and blood lipid levels.
- If you have diabetes, continue to closely monitor blood sugar levels. If you are at increased risk of developing diabetes (borderline blood sugar levels, significant overweight, high blood lipid levels or high blood pressure), monitoring by a doctor and periodic blood tests are necessary during the course of treatment with this medicine.

If you accidentally took a higher dosage
If you took an overdose or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting without explicit instruction from a doctor!

If you forgot to take this medicine at the scheduled time, take a dose as soon as you remember, but never take a double dose.

If you stop taking the medicine
If you want to stop using the medicine, consult a doctor or pharmacist.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor. Reduction of the dosage is usually done gradually.
- Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
- This medicine and any other medicine must be kept in a safe place, out of the reach of children and/or infants in order to avoid poisoning.
- If you have further questions regarding use of the medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS:

As with any medicine, use of Atorvastatin Teva 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.

Discontinue use of the medicine and refer to a doctor immediately if:
You develop a severe allergic reaction which causes swelling of the face, tongue and throat and you suffer from breathing difficulties (rare). You develop a severe skin reaction, which includes peeling and swelling of the skin, blisters on the skin, mouth, eyes, or genitals and fever (rare). You develop a rash with pink-red spots on the palms of the hands and soles of the feet (rare). You develop muscle weakness, muscle tenderness or pain, and if you simultaneously feel bad and have a high fever. This may result from muscle tissue breakdown which can be life-threatening and lead to kidney problems (rare). You suffer from sudden bleeding or bruises – this may indicate liver problems. Refer to the doctor immediately for advice (very rare).

Additional side effects:
Common side effects – inflammation of the nasal passages, sore throat, nose bleed, allergic reaction, increased blood sugar levels (if you have diabetes, continue to closely monitor blood sugar levels), increase in blood creatine kinase, headache, nausea, constipation, flatulence, indigestion, diarrhea, joint and muscle pains, back pains, blood test results that indicate impaired liver function.
Uncommon side effects – loss of appetite, weight gain, decreased blood sugar levels (if you have diabetes, continue to closely monitor blood sugar levels), nightmares, insomnia, dizziness, numbness or tingling in the fingers and toes, decreased sensation of pain or touch, altered sense of taste, memory loss (forgetfulness), blurred vision, ringing in the ears/head, vomiting, hiccups, abdominal pain, pancreatitis (which may cause severe abdominal pain), liver inflammation, rash, itching, urticaria, hair loss, neck pain, muscle fatigue, fatigue, feeling unwell, weakness, chest pain, swelling of the ankles (edema), fever, white blood cells in the urine.
Rare side effects - visual disturbances, unexpected bleeding and bruising, yellowing of the skin and whites of the eyes, tendon injury.
Very rare side effects – hearing loss, enlargement of the breasts in women and men.
Side effects reported with use of other statins - sexual function difficulties, depression - refer to a doctor!, shortness of breath, persistent cough, fever, interstitial pulmonary disease that can be manifested by shortness of breath, dry cough and worsening of general health status (e.g., fatigue, weight loss and fever) - refer to a doctor immediately!, diabetes, cognitive disturbances (e.g., memory loss, confusion, forgetfulness) - usually, these effects were not severe and disappeared after discontinuing use of the medicine - refer to a doctor!

If a side effect occurs, if any of the side effects worsen or if you are suffering from a side effect not mentioned in this leaflet, consult 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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- 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 without explicit instruction from 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. In any case of doubt, consult the pharmacist who dispensed the medicine to you.
- Store below 25°C. Store in the original package.
- Do not store different medicines in the same package.
- Bottle package: The preparation can be used for up to 30 days after first opening the bottle, but not beyond the expiry date.

6. FURTHER INFORMATION

- **In addition to the active ingredient, the medicine also contains (all 4 strengths):** Lactose monohydrate, crospovidone, magnesium stearate, magnesium carbonate, colloidal anhydrous silica, polydextrose, titanium dioxide, hypromellose, macrogol/ PEG 4000.
- **What the medicine looks like and the contents of the package:**
  Atorvastatin Teva 10 mg:
  White to off-white capsule-shaped tablet, debossed with "93" on one side and "7310" on the other side.
  Atorvastatin Teva 20 mg:
  White to off-white capsule-shaped tablet, debossed with "93" on one side and "7311" on the other side.
  Atorvastatin Teva 40 mg:
  White to off-white capsule-shaped tablet, debossed with "93" on one side and "7312" on the other side.
  Atorvastatin Teva 80 mg:
  White to off-white capsule-shaped tablet, debossed with "93" on one side and "7313" on the other side.
  The package for each Atorvastatin Teva strength contains 30 tablets.
  The bottle package contains a desiccating device and an oxygen absorbing device - do not swallow them. They should be left in the container.
- **Registration holder and address:** Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petach Tikva.
- **Registration number of the medicine in the National Drug Registry of the Ministry of Health:**
  10 mg: 143.33.31993
  20 mg: 143.34.31994
  40 mg: 143.35.31995
  80 mg: 143.36.31996
- This leaflet was checked and approved by the Ministry of Health on 21.01.16.

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