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

The medicine is dispensed with a doctor's prescription only

Pravastatin Teva 20 mg

Tablets

Composition

Each tablet contains:

Pravastatin sodium 20 mg

Pravastatin Teva 40 mg

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Composition

Each tablet contains:

Pravastatin sodium 40 mg

For information on inactive and allergenic ingredients, 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?

- Reduction of blood cholesterol and triglyceride levels.
- Reduction of the risk of myocardial infarction and extension of life expectancy in hypercholesterolemic patients with no evidence of coronary disease.
- Reduction of the risk of overall mortality by lowering mortality due to heart diseases, and reduction of the risk of heart attack in patients with atherosclerosis and average or high cholesterol level.

Further information:

- Pravastatin Teva is used to reduce high levels of "bad" cholesterol and to increase levels of "good" cholesterol in the blood when changes in diet and physical activity have failed to adequately do this. While cholesterol is essential for the proper functioning of the body, if its levels in the blood are too high, it can accumulate on the walls of the arteries. Eventually, blood vessels may become blocked. This condition is called hardening of the arteries (atherosclerosis). This condition can lead to chest pain (angina pectoris), when a blood vessel in the heart is partially blocked, heart attack (myocardial infarction), when a blood vessel in the heart is fully blocked, stroke (cerebrovascular accident), when a blood vessel in the brain is fully blocked. Most cholesterol is produced by the liver and only a small amount of cholesterol comes from the diet. The body produces most cholesterol at night.
- Although you may be on a low-fat diet, blood tests can show that your blood fat (including cholesterol) levels are still high. A high cholesterol level is generally identified as a contributor to risk of heart disease. Additional factors, such as pre-existing heart disease, high blood pressure, diabetes, being overweight, lack of physical activity and smoking, can also significantly increase the risk of development or progression of heart disease.

Therapeutic group:

Statins (or HMG-CoA reductase enzyme inhibitors). This group lowers the amount of cholesterol and triglycerides (fats) in the blood.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient pravastatin or to any of the additional ingredients contained in the medicine (see section 6 – "Further information").
- you are suffering from an active liver disease.
- you are pregnant, or there is a possibility that you will become pregnant ,or if you are breastfeeding (see "Pregnancy and breastfeeding").

Special warnings regarding use of the medicine

Before treatment with Pravastatin Teva, tell the doctor if:

- you have or have had myasthenia (a disease characterized by general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition or lead to the occurrence of myasthenia (see section 4 – "Side effects").
- you have kidney problems.
- you are over 70 years of age.
- you have suffered in the past from liver problems.
- you have an underactive thyroid (hypothyroidism).
- you have a hereditary muscle disorder or you have a family history of similar problems.
- you have suffered in the past from side effects affecting the muscles when taking another cholesterol-lowering medicine, such as a statin (a medicine that inhibits the HMG-CoA reductase enzyme) or a fibrate (e.g., gemfibrozil).
- during the course of treatment you experience unexplained cramps or muscle pain – inform the doctor immediately.
- you are suffering from problems of alcohol abuse (routine consumption of large amounts of alcohol).
- you are using or have used in the last 7 days a medicine called fusidic acid (a medicine for bacterial infection), orally or by injection. The combination of fusidic acid with Pravastatin Teva can lead to serious muscle problems (rhabdomyolysis).

If any of the conditions described above apply to you, the doctor will tell you to perform a blood test before, and most likely during, treatment. These blood tests will serve to evaluate the risk of muscle-associated side effects.

The doctor will tell you to perform a blood test before you start taking pravastatin and if you have symptoms of liver problems during the course of treatment with pravastatin. The objective of the test is to check your liver function. Your doctor may want to perform blood tests to check how your liver is functioning after treatment with pravastatin is initiated.

In addition, before treatment with Pravastatin Teva, tell the doctor if:

- you are suffering from severe respiratory failure.

If you have diabetes or are at risk of developing diabetes, the doctor will monitor your tests frequently during the course of treatment with this medicine. If your blood sugar and fat levels are high, you are overweight and have high blood pressure, you are most likely at risk of developing diabetes.

In addition, tell the doctor if you experience prolonged muscle weakness. Additional tests and medicines may be necessary to diagnose and treat this condition.

Drug interactions

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

- Medicines to lower cholesterol from the fibrate group, e.g., fenofibrate or gemfibrozil, a medicine that reduces the body's immune protection (ciclosporin an immunosuppressant administered after an organ transplant) or another medicine to lower the level of cholesterol (nicotinic acid [vitamin B3]) – these medicines can disrupt the way Pravastatin Teva acts in the body.
- Medicines known to bind bile acid (a group of medicines that prevent bile acid from being reabsorbed into the digestive system, thereby promoting the conversion of cholesterol to bile acid and reducing the level of fats in the blood), e.g., cholestyramine, colestipol. If you are also taking a bile acid-binding medicine, see section 3 – "How should you use the medicine?".
- Medicines to treat bacterial infections (erythromycin, clarithromycin or fusidic acid antibiotics). If you need to use oral fusidic acid to treat a bacterial infection, you will need to temporarily stop using Pravastatin Teva. The doctor will tell you when it is safe to resume Pravastatin Teva treatment. Use of Pravastatin Teva together with fusidic acid may rarely lead to muscle weakness, tenderness or pains (rhabdomyolysis). See further information regarding rhabdomyolysis in section 4 – "Side effects".
- If you are taking a medicine called "vitamin K antagonist" to treat and prevent formation of blood clots, tell the doctor before taking Pravastatin Teva since concomitant use of a vitamin K antagonist and Pravastatin Teva may increase blood test values used to monitor vitamin K antagonist treatment.

Taking pravastatin with any of the following medicines can increase the risk of muscle problems:

- Colchicine (used to treat gout)
- Nicotinic acid (used to lower high blood cholesterol level)
- Rifampicin (used to treat tuberculosis)
- Lenalidomide (used to treat a cancer called multiple myeloma).

Use of the medicine and food

Pravastatin Teva can be taken with or without food.

Use of the medicine and alcohol consumption

Limit alcohol consumption to a minimum. If you want to drink while using the medicine, drink small amounts of alcohol only. Even if you drank alcohol once, do not stop using the medicine. If you are concerned about the amount of alcohol that you can drink while taking the medicine, consult the doctor.

Pregnancy and breastfeeding

Do not use Pravastatin Teva:

- if you are pregnant or breastfeeding (since this medicine passes into breast milk), or are planning a pregnancy.
- if you might become pregnant, unless you are using reliable **non**-hormonal contraceptives (hormonal contraceptives are, for example, pills or another hormonal preparation to prevent pregnancy). It is important that you consult the doctor about this.
- if you become pregnant during the course of treatment with Pravastatin Teva, stop taking this medicine as soon as you find out about it.

Driving and operating machinery

Pravastatin Teva may cause dizziness, blurred vision or double vision during the course of treatment. If you experience these effects, do not drive and do not operate machinery. Make sure that you are fit to drive and operate machinery before setting out to do so.

Important information about some of the ingredients of the medicine

- Patients with an intolerance to lactose must take note that Pravastatin Teva tablets contain a small amount of lactose. If you have been told by the doctor that you have an intolerance to certain sugars, refer to the doctor before taking this medicine.
- This medicine contains less than 23 mg sodium per tablet and is therefore considered 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 preparation dosage and treatment regimen. The doctor will explain the importance of a low-fat diet in addition to taking Pravastatin Teva, and you should continue this diet throughout the course of treatment.

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

- For treatment of high blood cholesterol and fat levels: 10-40 mg, once a day, preferably in the evening.
- For prevention of heart and blood vessel diseases: 40 mg, once a day, preferably in the evening.
- **Do not exceed the recommended dose.**

Duration of treatment

The doctor will indicate the duration of Pravastatin Teva treatment. This medicine should be used regularly, and for the period of time as determined by your doctor, even if it is for a long time. Do not stop treatment on your own.

Method of administration

It is preferable to swallow the tablet with a glass of water. The tablet can be taken with or without food.

Crushing/halving/chewing

Pravastatin Teva 20 mg: Do not halve the tablet. If a 10 mg dosage of pravastatin is needed, other preparations containing 10 mg pravastatin approved in Israel can be used.

Pravastatin Teva 40 mg: The tablet can be halved.

All dosages: To ease swallowing, you can, if necessary, crush the tablet, or break it into smaller pieces, but swallow all parts of the tablet immediately afterwards.

There is no information regarding chewing.

- If you are also taking bile acid-binding-type medicines (e.g., cholestyramine or colestipol), take Pravastatin Teva at least one hour before taking these medicines, or at least four hours after taking these medicines, since Pravastatin Teva absorption may be affected by bile acid-binding-type medicines if taken close to each other.

Liver or kidney problems

If you have suffered in the past from liver problems or if you are suffering from kidney problems, the doctor may prescribe a lower dosage.

If you accidentally took a higher dosage, 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 forgot to take the medicine at the designated time, take a dose as soon as you remember, unless it is almost time for you to take the next dose. Do not take a double dose to compensate for a forgotten dose.

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 with the doctor.

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 Pravastatin Teva may cause side effects in some 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 refer to a doctor immediately if:

• you suffer from sudden severe allergic reactions, including swelling of the face, lips, tongue or trachea, which can cause great difficulty in breathing. This reaction is very rare and when it occurs, it can be severe. If this happens, tell the doctor immediately • you are suffering from a breathing problem, including persistent cough and/or shortness of breath or fever.

Inform the doctor immediately if:

• you develop unexplained or prolonged muscle aches, tenderness, weakness or spasms, especially if you do not feel well or have a high fever at the same time • in very rare cases, muscle problems can be serious (rhabdomyolysis) and may lead to severe, life-threatening kidney disease.

Effect on the skin and hair: rash.

Additional side effects:

Uncommon side effects (may affect up to 1 patient in 100):

• insomnia • dizziness • tiredness• headache or sleep disturbances • blurred or double vision • indigestion • nausea • vomiting • stomach pain or discomfort • pain in the chest as a result of stomach acidity • diarrhea • constipation • flatulence • itching • acne • urticaria • rash • scalp and hair problems (including hair loss) • bladder-related problems (painful or frequent urination, nocturia) • sexual function disturbances • muscle and joint aches.

Very rare side effects (may affect up to 1 patient in 10,000):

• weakness, problems with sense of touch, including burning or tingling sensation or numbness, which can indicate neural damage (especially if you use pravastatin for a long period of time) • serious skin disease (lupus erythematous-like syndrome) • inflammation of the liver or pancreas, jaundice (identified by yellowing of the skin and whites of the eyes) • very rapid death of liver cells (fulminant liver necrosis) • tendinitis which may become complicated and lead to tendon rupture • increased transaminases (a group of enzymes naturally found in the blood), which can be a sign of liver problems. The doctor may perform periodic tests to monitor your condition.

Side effects of unknown frequency (the frequency cannot be estimated from the available data):

• constant muscle weakness • diabetes: the frequency will depend on the presence or absence of risk factors (fasting blood glucose level of 5.6 mmol/L, BMI > 30 kg/m^2, high triglyceride levels, history of high blood pressure) • dermatomyositis (a condition characterized by inflammation of the muscles and skin) • liver failure • myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing) • ocular myasthenia (a disease causing eye muscle weakness).

Consult with the doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing or shortness of breath.

The following side effects have been reported for several statins (unknown frequency):

• nightmares • memory loss • depression • breathing problem, including persistent cough and/or shortness of breath or fever • diabetes: occurrence of this side effect is more likely if you have high blood sugar and fat levels, you are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.

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

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.
- **Store in a dry place, below 25°C. Keep in the original package in order to protect from light.**
- Do not dispose of medicines in the waste water or waste bin. Ask the pharmacist how to dispose of medicines that are not in use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Lactose monohydrate, crospovidone, magnesium stearate.

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

Pravastatin Teva 20 mg tablets:

A round, creamy-white, convex tablet, plain on both sides.

Each package contains 30 tablets packaged in blisters (trays).

Pravastatin Teva 40 mg tablets:

An elongated, creamy-white tablet with a score line on one side and the letter "P" debossed on the other side.

Each package contains 30 tablets packaged in blisters (trays).

Name of Manufacturer and License Holder and its Address:

Teva Israel Ltd.,

124 Dvora HaNevi'a St., Tel Aviv.

The leaflet was revised in July 2023 according to MOH guidelines.

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

Pravastatin Teva 20 mg: 124.64.30379

Pravastatin Teva 40 mg: 124.65.30380