

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

The medicine is dispensed with  
a doctor's prescription only

# Ezetimibe Teva

## Tablets

### Composition

Each tablet contains:

Ezetimibe 10 mg

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

**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 to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

Ezetimibe Teva is not intended for children below the age of 10.

### 1. WHAT IS THE MEDICINE INTENDED FOR?

Ezetimibe Teva is intended for patients with:

- Primary heterozygous familial and non-familial hypercholesterolemia (conditions in which there is a high level of cholesterol in the blood), as a treatment given on its own, or in combination with a statin (HMG-CoA reductase inhibitor), as an addition to a diet.

- Homozygous familial hypercholesterolemia (a condition in which there is a high level of cholesterol in the blood) in combination with a statin and other treatments to lower blood lipid levels (e.g., the removal of lipids – LDL apheresis).

- Homozygous familial sitosterolemia (a disorder of absorption and removal of lipids from the digestive system).

Ezetimibe Teva is used as a medicine to lower high blood lipid levels.

### Therapeutic group

Ezetimibe belongs to a group of medicines called *CAI* (Cholesterol Absorption Inhibitors), which inhibit the absorption of cholesterol in the intestines.

Ezetimibe Teva is sometimes given in combination with medicines from the statin family (e.g., simvastatin, atorvastatin, etc.); in this case, read the statin's patient package insert carefully before starting treatment and consult your doctor.

### 2. BEFORE USING THE MEDICINE

#### Do not use the medicine:

- If you are sensitive (allergic) to ezetimibe or any of the other ingredients of Ezetimibe Teva (see also section 6 "Further Information").
- In combination with a statin, if you currently have liver problems.
- In combination with a statin, if you are pregnant or breastfeeding.

If you are taking Ezetimibe Teva together with a statin, read the patient package insert of that particular medicine.

If you think that any of these are relevant to you, do not take the tablets until you have consulted with your doctor.

### Special warnings regarding use of the medicine

- Tell your doctor about all your medical conditions, including allergies.

- Your doctor should refer you to perform a blood test before you start taking Ezetimibe Teva with a statin. This is to check how well your liver is functioning.

- Your doctor may also wish to refer you for blood tests to check how well your liver is functioning after you start taking Ezetimibe Teva with a statin.

If you have moderate or severe liver problems, Ezetimibe Teva is not recommended.

### Children and adolescents

Do not give this medicine to children and adolescents (aged 10 to 17 years) unless prescribed by a specialist, as there is limited information about the safety and efficacy of the medicine.

This medicine is not intended for children below the age of 10.

### Drug interactions:

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

In particular, tell your doctor if you are taking a medicine/s with any of the following active ingredients:

- Ciclosporin (often used in patients who have undergone organ transplantation)
- Medicines with an active ingredient to prevent the formation of blood clots, such as warfarin, phenprocoumon, acenocoumarol or fluindione (anticoagulants)
- Colestyramine (also used to lower cholesterol levels), because it affects the way ezetimibe works
- Fibrates (also used to lower cholesterol levels)

The safety and efficacy of a combination treatment with ezetimibe and certain cholesterol-lowering medicines, the fibrates, have not been established.

### Use of the medicine and food

Ezetimibe Teva can be taken with or without food.

### Pregnancy and breastfeeding

Do not take Ezetimibe Teva with a statin if you are pregnant, trying to become pregnant or think you are pregnant. If you become pregnant while taking Ezetimibe Teva with a statin, stop taking both medicines immediately and tell your doctor. There is no experience with the use of ezetimibe without a statin during pregnancy. Consult with your doctor before taking Ezetimibe Teva if you are pregnant.

Do not take Ezetimibe Teva with a statin if you are breastfeeding, because it is not known whether the medicines are passed into breast milk. Ezetimibe Teva without a statin should not be taken if you are breastfeeding. Consult with your doctor. Consult your doctor or pharmacist before taking any medicine.

### Driving and operating machinery

Ezetimibe Teva is not expected to impair your ability to drive or operate machinery. In all events, it should be taken into account that some people could feel dizzy after taking Ezetimibe Teva.

### Important information about some of the ingredients of the medicine

Ezetimibe Teva tablets contain a sugar called lactose. If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

This medicine contains less than 23 mg of sodium per tablet, and is therefore considered to be sodium free.

### 3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Continue taking your other medicines for lowering cholesterol levels, unless your doctor instructed you to stop. Check with your doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine. Your doctor will determine the dosage and the duration of treatment.

Swallow the medicine with a small amount of water. There is no information regarding crushing/halving/chewing the tablets.

Before starting treatment with Ezetimibe Teva, you must start dieting to lower your cholesterol levels. You should adhere to this cholesterol-lowering diet while taking Ezetimibe Teva.

### The recommended dose is generally:

One Ezetimibe Teva 10 mg tablet by mouth, once a day.

### Do not exceed the recommended dose.

Ezetimibe Teva can be taken at any time of the day. It may be taken with or without food. If the doctor prescribed you Ezetimibe Teva in combination with a statin, both medicines can be taken at the same time. In this case, please read the instructions for administration in that particular medicine's patient package insert.

If the doctor prescribed you Ezetimibe Teva in combination with an additional cholesterol-lowering medicine containing the active ingredient cholestyramine or any other medicine containing a bile acid sequestrant, you should take Ezetimibe Teva at least two hours before or four hours after taking the bile acid sequestrant. Ezetimibe Teva is not intended for children below the age of 10.

### If you took more Ezetimibe Teva than you should have

Please contact your doctor or pharmacist.

If you took an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room, and bring the package of the medicine with you.

### If you forget to take Ezetimibe Teva

Do not take a double dose to make up for the forgotten tablet. Take the regular dose of Ezetimibe Teva at the usual time the next day.

### If you stop taking Ezetimibe Teva

Talk to your doctor or pharmacist because your cholesterol level may rise again.

### How can you contribute to the success of the treatment?

Complete 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 with the doctor.

**Do not take medicines in the dark! Check the label and the dose each time you take the 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 Ezetimibe 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.

The following terms are used to describe the frequency at which side effects have been reported:

- Very common (may affect more than one in 10 patients)
- Common (may affect up to one in 10 patients)
- Uncommon (may affect up to one in 100 patients)
- Rare (may affect up to one in 1,000 patients)
- Very rare (may affect up to one in 10,000 patients, including isolated reports).

**Contact your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness. This is because on rare occasions, muscle problems, including muscle breakdown resulting in kidney damage, can be serious and may become a potentially life-threatening condition.**

Allergic reactions, including swelling of the face, lips, tongue and/or throat that may cause difficulty in breathing or swallowing (which require immediate treatment) have been reported during use of the medicine. When ezetimibe has been used alone, the following side effects have been reported: Common: abdominal pain; diarrhea; flatulence; feeling tired.

Uncommon: elevations in some laboratory blood test results for liver (transaminases) or muscle (CK) function; cough; indigestion; heartburn; nausea; joint pain; muscle spasms; neck pain; decreased appetite; pain; chest pain; hot flush; high blood pressure.

Additionally, when used with a statin, the following side effects have been reported: Common: elevations in some laboratory blood test results for liver function (transaminases); headache; muscle pain, tenderness or weakness.

Uncommon: tingling sensation; dry mouth; itching; rash; hives; back pain; muscle weakness; pain in arms and legs; unusual tiredness or unusual weakness; swelling, especially of the hands and feet.

When used with fenofibrate, the following common side effect has been reported: abdominal pain.

Additionally, the following side effects have been reported: dizziness; muscle pain; liver problems; allergic reactions including rash and hives; raised red rash, sometimes with target-shaped lesions (erythema multiforme); muscle pain, tenderness or weakness; muscle breakdown; gallstones or inflammation of the gallbladder (which may cause abdominal pain, nausea, vomiting); inflammation of the pancreas, often with severe abdominal pain; constipation; reduction in blood cell counts, which may cause bruising/bleeding (thrombocytopenia); tingling sensation; depression; unusual tiredness or unusual weakness; shortness of breath.

**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 the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://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 this medicine below 25°C.

Do not dispose of medicines into the wastewater or a household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help to protect the environment.

### 6. FURTHER INFORMATION

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

Lactose monohydrate, croscarmellose sodium, croppovidone, microcrystalline cellulose, hypromellose, sodium lauryl sulfate, magnesium stearate.

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

Capsule shaped, white to cream colored tablets, debossed with 713 on one side and plain on the other side.

Each package contains 30 tablets in trays or in a bottle. Not all packages may be marketed.

### Name of License Holder and Manufacturer and its Address:

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

This leaflet was revised in August 2021 according to MOH guidelines.

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

163.59.35380