

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

The medicine is dispensed with  
a doctor's prescription only

## Ezecor Tablets

### Composition

Each tablet contains:  
Ezetimibe 10 mg

For the list of inactive and allergenic ingredients in the preparation, see section 6: "Further information" and section 2: "Before using the medicine".

### 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 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.
- **Ezecor** is not intended for children under the age of 10.

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

**Ezecor** is a medicine used to lower high levels of fat in the blood.

**Ezecor** is sometimes given in combination with medicines from the statin family (e.g., simvastatin, atorvastatin, etc.); in this case, carefully read the patient leaflet of the statin before starting treatment and consult your doctor.

### Therapeutic group:

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

### 2. BEFORE USING THE MEDICINE

#### Do not use the medicine:

- if you are sensitive (allergic) to ezetimibe or to any of the other ingredients contained in the medicine (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 **Ezecor** together with a statin, please read the patient leaflet of that additional medicine.

**If you think that the above applies to you, do not take the medicine until you consult with your doctor.**

### Special warnings regarding use of the medicine

- Tell your doctor of all your medical conditions, including allergies.
- The doctor should refer you to do blood tests before you start taking **Ezecor** with a statin. This is in order to check how well your liver is functioning.
- After starting treatment of **Ezecor** with a statin, your doctor may also want to refer you for blood tests in order to check how well your liver is functioning.

**Ezecor** is not recommended if you are suffering from moderate to severe liver problems.

### 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, tell your doctor if you are taking medicine(s) with one of the following:

- Ciclosporin (often used in patients who have undergone an organ transplantation)
- Medicines with an active ingredient to prevent blood clots, such as warfarin, phenprocoumon, acenocoumarol or flutidione (anticoagulants)
- Cholestyramine (also used to lower cholesterol), since it affects the way **Ezecor** works
- Fibrates (also used to lower cholesterol)  
The safety and efficacy of combined treatment of **Ezecor** and cholesterol-lowering medicines from the fibrate group have not been determined.

### Use of the medicine and food

**Ezecor** can be taken with or without food.

### Pregnancy and breastfeeding

Do not take **Ezecor** with a statin if you are pregnant, trying to become pregnant or think you are pregnant. If you become pregnant while taking **Ezecor** with a statin, stop taking the two medicines immediately and tell your doctor. There is no information about use of **Ezecor** without a statin during the course of pregnancy. Consult with your doctor before taking **Ezecor** if you are pregnant.

Do not take **Ezecor** with a statin if you are breastfeeding, since it is not known whether these medicines pass into breast milk. **If you**

**are taking Ezecor with or without a statin, and you want to breastfeed, consult a doctor before taking the medicinal treatment, as well as before taking any other medicine.**

### Driving and using machines

**Ezecor** is not expected to impair your ability to drive or operate machines. However, take into account that some people may feel dizzy after taking **Ezecor**.

### Children and adolescents

Do not give this medicine to children and adolescents (10 to 17 years of age), unless prescribed by a specialist, because there are limited data on safety and efficacy.

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

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

#### Ezecor contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet and is essentially sodium-free.

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

Always use the preparation according to the doctor's instructions. Continue taking other cholesterol-lowering medicines, unless your doctor has instructed you to stop. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

Your doctor will determine the dosage and duration of the treatment.

Swallow the medicine with a small amount of water.

Do not halve the tablet. There is no information about crushing or chewing the tablet.

Before starting treatment with **Ezecor**, you must start a diet to lower your cholesterol. Adhere to this diet while taking **Ezecor**.

#### The recommended dosage is usually:

One **Ezecor** tablet, taken orally, once a day. **Ezecor** can be taken at any hour of the day. Can be taken with or without food.

#### Do not exceed the recommended dose.

If the doctor has prescribed **Ezecor** in combination with a statin for you, the two medicines can be taken at the same time. In this case, please read the dosage instructions in the package leaflet of the additional medicine. If the doctor prescribed for you **Ezecor** in combination with another cholesterol-lowering medicine containing the active ingredient cholestyramine or any other medicine containing a bile acid sequestrant,

take **Ezecor** at least two hours before or four hours after taking the bile acid sequestrant. **Ezecor** is not intended for children under the age of 10.

#### If you took more Ezecor than you should

Please contact your doctor or pharmacist. If you took an overdose, or if a child has 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 Ezecor

Do not take a double dose to compensate for a forgotten dose. Take the regular **Ezecor** dose, at the usual time, the following day.

#### If you stop taking Ezecor

Speak to your doctor or pharmacist since your cholesterol may increase again.

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

Complete the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with this 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 **Ezecor** 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 how often side effects have been reported:

- Very common (may affect more than 1 in 10 patients).
- Common (may affect up to 1 in 10 patients).
- Uncommon (may affect up to 1 in 100 patients).
- Rare (may affect up to 1 in 1,000 patients).
- Very rare (may affect up to 1 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, which may result 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 in general use.

When using **Ezecor** alone, the following side effects were reported:

- Common: abdominal pain; diarrhea; flatulence; feeling tired.
- Uncommon: increase in some laboratory blood tests of liver (transaminases) or muscle (CK) function; cough; digestive disorders; 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 were reported:

- Common: increase in some laboratory blood tests of 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 weakness; swelling, especially in the hands and feet.

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

Additionally, the following side effects have been reported in general use: dizziness; muscle aches; 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, occasionally with severe abdominal pain; constipation; reduction in blood cell counts, which may cause bruising/bleeding (thrombocytopenia); tingling sensation; depression; unusual tiredness or 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 on the link "[Reporting 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.

Additionally, you can report to "[Unipharm Ltd.](#)".

### 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 **Ezecor** after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of the indicated month.

Store at a temperature below 25°C and in a dry place protected from light.

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

### 6. FURTHER INFORMATION

#### What does Ezecor contain?

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

Mannitol, Microcrystalline cellulose, Croscarmellose sodium, Povidone, Sodium lauryl sulfate, Magnesium stearate.

#### What does Ezecor look like and the contents of the package

**Ezecor** is packaged in trays (blisters) which are inserted in a carton package. Each package contains 5, 7, 10, 14, 15, 20, 28, 30 or 56 tablets. Not all package sizes may be marketed.

**Ezecor** are round, biconvex, white tablets.

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

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

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

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