Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986
This medicine is dispensed with a doctor's prescription only

Ezetimibe Taro 10 mg
Tablets

Active ingredient
Each tablet contains 10 mg ezetimibe
Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed for you. 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.

1. What is this medicine intended for?

Ezetimibe Taro 10 mg is intended for patients with:

- primary heterozygous familial and non-familial hypercholesterolemia (conditions in which there is a high cholesterol level in the blood), as a single treatment or in combination with a statin (HMG-CoA reductase inhibitor) as adjunctive to diet.
- homozygous familial hypercholesterolemia (a condition in which there is a high cholesterol level in the blood), in combination with a statin and other treatments for reduction of lipid levels in the blood (e.g. LDL apheresis).
- homozygous familial sitosterolemia (disorder of lipid absorption and removal from the gastrointestinal tract).

Therapeutic group:
Ezetimibe is a member of a class of medicines called CAI (cholesterol absorption inhibitors), which inhibit intestinal absorption of cholesterol.

Ezetimibe Taro 10 mg is used to lower high blood levels of lipids.
Ezetimibe Taro 10 mg is sometimes given together with medicines from the statin class (e.g., simvastatin, atorvastatin, etc.). If that is the case, read the statin's patient information leaflet carefully before starting treatment, and consult your doctor.

2. Before using this medicine

Do not use this medicine:

- if you are sensitive (allergic) to the active ingredient (ezetimibe) or to any of the other ingredients in this medicine (see section 6);
- together with a statin, if you currently have liver problems;
- together with a statin, if you are pregnant or breastfeeding.

Special warnings about using this medicine
- Tell your doctor about your medical conditions, including allergies.
- If you have moderate or severe liver problems, **Ezetimibe Taro 10 mg** 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, because the information about safety and efficacy is limited.

This medicine is not intended for children under 10 years old.

Tests and follow-up
- Your doctor should refer you for blood tests before you start taking **Ezetimibe Taro 10 mg** with a statin. This is done to check how well your liver is working.
- Your doctor may also want to refer you for blood tests that check how well your liver is working after you start taking **Ezetimibe Taro 10 mg** with a statin.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:
- ciclosporin (often used in organ transplant patients)
- medicines with an active ingredient for preventing blood clots, such as warfarin, phenprocoumon, acenocoumarol or fluindione (anticoagulants)
- colestyramine (also used to lower cholesterol), because it affects the way **Ezetimibe Taro 10 mg** works
- fibrates (also used to lower cholesterol).
  The safety and efficacy of the combined use of **Ezetimibe Taro 10 mg** and certain cholesterol lowering medicines called fibrates have not been established.

Using this medicine and food
You can take **Ezetimibe Taro 10 mg** with or without food.

Pregnancy and breastfeeding
Do not take **Ezetimibe Taro 10 mg** with a statin if you are pregnant, are trying to become pregnant or think you may be pregnant. If you become pregnant while taking **Ezetimibe Taro 10 mg** with a statin, stop taking both medicines and tell your doctor. There is no experience of using **Ezetimibe Taro 10 mg** without a statin during pregnancy. Ask your doctor for advice before using **Ezetimibe Taro 10 mg** if you are pregnant.
Do not take **Ezetimibe Taro 10 mg** with a statin if you are breastfeeding, because it is not known if the medicine passes into breast milk.
Ezetimibe Taro 10 mg without a statin should not be used if you are breastfeeding. Ask your doctor for advice.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Ezetimibe Taro 10 mg is not expected to interfere with your ability to drive or to use machinery. However, take into account that some people may get dizzy after taking **Ezetimibe Taro 10 mg**.

Important information about some of this medicine's ingredients
Ezetimibe Taro 10 mg tablets contain a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
Ezetimibe Taro 10 mg tablets contain less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to use this medicine?

Always take **Ezetimibe Taro 10 mg** exactly as your doctor has told you. Continue taking your other cholesterol lowering medicines unless your doctor tells you to stop. Check with your doctor or pharmacist if you are not sure.
Your doctor will determine your dosage and duration of treatment.
The recommended dose is usually:
one **Ezetimibe Taro 10 mg** tablet by mouth, once a day.

Do not exceed the recommended dose.
You can take **Ezetimibe Taro 10 mg** at any time of the day. You can take it with or without food.

If your doctor has prescribed **Ezetimibe Taro 10 mg** along with a statin, both medicines can be taken at the same time. In this case, please read the dosage instructions in the package leaflet of that other medicine.
If your doctor has prescribed **Ezetimibe Taro 10 mg** along with another medicine for lowering cholesterol that contains the active ingredient colestyramine or any other medicine containing bile acid sequestrant, you should take **Ezetimibe Taro 10 mg** at least 2 hours before or 4 hours after taking the bile acid sequestrant.

Ezetimibe Taro 10 mg is not intended for children under 10 years old.

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

Before you start treatment with **Ezetimibe Taro 10 mg**, you must start a cholesterol-reducing diet. Continue this cholesterol-reducing diet while you are taking **Ezetimibe Taro 10 mg**.

If you take more Ezetimibe Taro 10 mg than you should
Please contact your doctor or pharmacist.
If you have taken an overdose, or if a child has accidentally swallowed some medicine, go to a hospital emergency room immediately and bring the medicine package with you.

If you forget to take Ezetimibe Taro 10 mg
Do not take a double dose to make up for a forgotten tablet; take your usual dose of **Ezetimibe Taro 10 mg** at the usual time on the next day.

If you stop taking Ezetimibe Taro 10 mg
Talk to your doctor or pharmacist because your cholesterol may rise again.

How can you contribute to the success of this treatment?
Complete the full course of treatment as advised by the doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. <u>Side effects</u>

Like all medicines, using **Ezetimibe Taro 10 mg** may cause side effects in some users.
Do not be alarmed by this list of side effects; you may not experience 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, includes 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 could become a life-threatening condition.

Allergic reactions, including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing (which requires treatment right away) have been reported in general use.

When **Ezetimibe Taro 10 mg** was used alone, the following side effects were reported:
Common: abdominal pain, diarrhoea, flatulence, feeling tired.
Uncommon: elevations in some laboratory blood tests of 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 were reported:
Common: elevations 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 often with severe abdominal pain, constipation, reduction in blood cell counts, which may cause bruising/bleeding (thrombocytopaenia), tingling sensation, depression, unusual tiredness or weakness, shortness of breath.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
Do not use **Ezetimibe Taro 10 mg** after the expiry date (exp. date) which is stated on package. The expiry date refers to the last day of the month.
Storage conditions: Store this medicine below 25°C. Protect from moisture.
Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:
lactose monohydrate, starch, croscarmellose sodium, povidone, sodium laurilsulfate, magnesium stearate.

What the medicine looks like and contents of the pack:
white to off-white, capsule-shaped tablets debossed with “E10” on one side.
Packs contain 30 or 90 tablets in a bottle.
Not all pack sizes may be marketed.

Registration holder’s name and address: Taro International Ltd., 14 HaKitor St., Haifa Bay 2624761.

Manufacturer’s name and address:
Ohm Laboratories, Inc., 14 Terminal Road, New Brunswick, NJ 08901 USA

Revised in June 2023 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health’s National Drug Registry: 172-45-36271-00