

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

The medicine is dispensed with a doctor's prescription only

TOREZ 10/10
Film-coated tablets

TOREZ 10/20
Film-coated tablets

TOREZ 10/40
Film-coated tablets

TOREZ 10/80
Film-coated tablets

Composition:

Each Torez 10/10 tablet contains:

Ezetimibe 10 mg and Atorvastatin (as calcium trihydrate) 10 mg

Each Torez 10/20 tablet contains:

Ezetimibe 10 mg and Atorvastatin (as calcium trihydrate) 20 mg

Each Torez 10/40 tablet contains:

Ezetimibe 10 mg and Atorvastatin (as calcium trihydrate) 40 mg

Each Torez 10/80 tablet contains:

Ezetimibe 10 mg and Atorvastatin (as calcium trihydrate) 80 mg

For a list of inactive and allergenic ingredients in the preparation, see in 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 **Torez**. If you have further questions, ask 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.
- **Torez** is intended for the treatment of adults over 18 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

Torez is used, in combination with diet,

- for the treatment of primary hypercholesterolemia (heterozygous familial and non-familial) or to decrease elevated fat levels in the blood (mixed hyperlipidemia) in adult patients who:
 - are not well controlled with a statin alone; or
 - are already treated with a statin and ezetimibe
- for the treatment of adult patients with a hereditary illness (homozygous familial hypercholesterolemia). The treatment may be given in combination with other treatments.
- If you have heart disease, to reduce the risk of cardiovascular events (such as heart attack, stroke, surgery to increase heart blood flow, or hospitalization due to chest pain).

Therapeutic group: Ezetimibe belongs to a group of medicines called CAI (cholesterol absorption inhibitors) that inhibit the intestinal absorption of

cholesterol. Atorvastatin belongs to a group of medicines called statins, which are HMG-CoA reductase enzyme inhibitors.

Torez works to reduce your cholesterol in two ways. It reduces cholesterol absorption in your digestive tract and in addition, reduces the amount of cholesterol your body makes by itself.

Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of LDL and HDL cholesterol.

LDL cholesterol is often called “bad” cholesterol because it can build up in the walls of your arteries and form plaque. Eventually, this plaque build-up can lead to a narrowing of the arteries. This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke.

HDL cholesterol is often called “good” cholesterol because it helps keep the bad cholesterol from building up in the arteries and protects against heart disease.

Triglycerides are another form of fat in your blood that may increase your risk for heart disease.

Torez does not help you lose weight.

2. BEFORE USING THE MEDICINE

Do not use Torez if:

- you are sensitive (allergic) to ezetimibe, atorvastatin or any of the additional ingredients contained in the medicine (see section 6 “Further information”).
- you have or have ever had a disease that affects the liver.
- you have had unexplained abnormal liver function blood tests.
- you are a woman able to have children and are not using reliable contraception.
- you are pregnant, trying to become pregnant or are breastfeeding.
- you use the combination of glecaprevir/pibrentasvir for the treatment of hepatitis C.

Special warnings regarding use of Torez

Before starting treatment with Torez, tell the doctor if:

- you have had a previous stroke with bleeding in the brain, or have small pockets of fluid in the brain from previous strokes.
- you have kidney problems.
- you have an underactive thyroid gland (hypothyroidism).
- you have had repeated or unexplained muscle aches or pains, a personal history or family history of muscle problems.
- you have had previous muscular problems during treatment with other lipid-lowering medicines (e.g., other “statins” or “fibrate” medicines).
- you regularly drink a large amount of alcohol.
- you have a history of liver disease.
- you are above the age of 70 years.
- you have been told by your doctor that you have an intolerance to certain sugars; contact your doctor before taking this preparation.
- you are taking, or have taken in the last 7 days, a medicine called fusidic acid (a medicine for treatment of bacterial infection) orally or by injection. The

combination of fusidic acid and **Torez** can lead to serious muscle problems (rhabdomyolysis).

- you have or have had myasthenia (a disease with generalized 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”).

Contact your doctor immediately if you experience unexplained muscle pain, tenderness or weakness while taking Torez. This is because, on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage. Atorvastatin is known to cause muscle problems, and cases of muscle problems have also been reported with ezetimibe.

Similarly, tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.

Check with your doctor or pharmacist before taking **Torez**:

- if you have severe respiratory failure.

If any of these apply to you (or you are not sure), talk to your doctor or pharmacist before taking **Torez**, because your doctor will need to carry out a blood test before and possibly during your **Torez** treatment to identify your risk of muscle-related side effects. The risk of muscle-related side effects, e.g., muscle breakdown (rhabdomyolysis), is known to increase when certain medicines are taken at the same time (see section 2 “Drug interactions”).

While you are taking this medicine, your doctor will closely monitor your condition if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

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

Avoid combined use of **Torez** and fibrates (medicines for lowering cholesterol) since the combination of **Torez** and fibrates has not been studied.

Children and adolescents

Torez is not intended for children and adolescents.

Drug interactions

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

There are medicines that may change the effect of **Torez** or their effect may be changed by **Torez** (see section 3 “How should the medicine be used?”). This type of interaction could make one or both of the medicines less effective. Alternatively, it could increase the risk or severity of side effects, including a severe side effect of a muscle-wasting condition known as “rhabdomyolysis” described in section 4 “Side effects”:

- ciclosporin (a medicine often used in organ transplant patients).
- erythromycin, clarithromycin, telithromycin, fusidic acid**, rifampicin (medicines for bacterial infections).
- ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole (medicines for fungal infections).

- gemfibrozil, other fibrates, nicotinic acid, colestipol, cholestyramine (medicines for regulating fat levels).
- some calcium channel blockers used to treat angina or high blood pressure, e.g., amlodipine, diltiazem.
- digoxin, verapamil, amiodarone (medicines to regulate your heart rhythm).
- medicines for the treatment of HIV, e.g., ritonavir, lopinavir, atazanavir, indinavir, darunavir, the combination of tipranavir/ritonavir, etc. (medicines to treat AIDS).
- some medicines for the treatment of hepatitis C, e.g., telaprevir, boceprevir and the combination of elbasvir/grazoprevir.
- daptomycin (a medicine used to treat complicated skin and skin structure infections and bacteremia).

****If you need to take oral fusidic acid to treat a bacterial infection, you will need to temporarily stop treatment with this medicine. Your doctor will tell you when it is safe to start taking Torez again. Taking Torez with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4 “Side effects”.**

- Other medicines known to interact with **Torez**
 - oral contraceptives (medicines for preventing pregnancy).
 - stiripentol (an anticonvulsant medicine for epilepsy).
 - cimetidine (a medicine used to treat heartburn and peptic ulcers).
 - phenazone (a painkiller).
 - antacids (medicines containing aluminum or magnesium for digestion problems).
 - warfarin, phenprocoumon, acenocoumarol or fluindione (medicines to prevent blood clots).
 - colchicine (used to treat gout).
 - St. John's wort (a medicine to treat depression).

Taking Torez with food, drink and alcohol

See section 3 for instructions regarding administration of **Torez**. Please note the following:

Grapefruit juice

Do not drink more than one or two small glasses of grapefruit juice per day, because large quantities of grapefruit juice can change the effects of **Torez**.

Alcohol

Avoid drinking too much alcohol when taking this medicine. For details, see section 2 “Special warnings regarding use of **Torez**”.

Pregnancy and breastfeeding

Do not take **Torez** if you are pregnant, are trying to become pregnant or think you may be pregnant.

Do not take **Torez** if you are able to become pregnant unless you use reliable contraceptive measures. If you became pregnant while taking **Torez**, stop taking it immediately and tell your doctor.

Do not take **Torez** if you are breastfeeding.

The safety of **Torez** during pregnancy and breastfeeding has not yet been proven.

Ask your doctor or pharmacist for advice before taking this medicine.

Driving and operating machinery

Torez is not expected to affect your ability to drive or operate machinery. Nonetheless, take into account that some people may feel dizzy after taking **Torez**.

Important information about some of the ingredients of the medicine

Torez contains lactose. If the doctor has told you that you have an intolerance to certain types of sugar, consult the doctor before taking this medicine.

Torez contains less than 1 mmol (23 mg) of sodium per tablet, meaning it is considered 'sodium-free'.

3. HOW SHOULD THE MEDICINE BE USED?

Always use the preparation according to the doctor's instructions. Check with your doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

Your doctor will determine the strength of the tablet appropriate for you, based on your current treatment and your personal risk status.

The dosage and treatment regimen will be determined by the doctor only.

- Before starting treatment with **Torez**, you must be on a cholesterol-lowering diet.
- Adhere to the cholesterol-lowering diet while taking **Torez**.

The usual dosage is generally:

One **Torez** tablet by mouth, once a day.

Torez can be taken at any time of the day. It can be taken with or without food. To make swallowing easier, if necessary, the tablet may be halved for immediate use. The two halves should be swallowed together immediately after halving.

There is no information regarding crushing/chewing.

Do not exceed the recommended dosage.

If your doctor has prescribed you **Torez** together with cholestyramine or another bile acid sequestrant (medicines for lowering cholesterol), take **Torez** at least two hours before or 4 hours after taking the bile acid sequestrant.

If you accidentally took a higher dose of Torez

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 Torez

Do not take another dose; take your regular amount of **Torez** at the usual time the next day.

Adhere to the treatment regimen as recommended by the doctor.

If you stop taking Torez

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting your 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 **Torez** may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

If you experience any of the following serious side effects or symptoms, stop taking your tablets and tell your doctor immediately or proceed to the nearest hospital emergency room.

- serious allergic reaction that causes swelling of the face, tongue and throat, and which can cause great difficulty in breathing.
- serious illness with severe peeling and swelling of the skin, blistering of the skin, mouth, eyes, genitals and fever; skin rash with pink-red blotches, especially on the palms of the hands or soles of the feet, which may blister.
- muscle weakness, tenderness, muscle pain or tear, red-brown discoloration of urine and particularly, if at the same time, you feel unwell or have a high fever; this may be caused by an abnormal muscle breakdown that can be life-threatening and lead to kidney problems.
- lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).

Consult your doctor as soon as possible if you experience problems with unexpected or unusual bleeding or bruising, because this may be suggestive of a liver problem.

Additional side effects:

Common side effects – effects that occur in 1-10 in 100 users:

- diarrhea
- muscle aches

Uncommon side effects – effects that occur in 1-10 in 1,000 users:

- influenza
- depression; trouble sleeping; sleep disorder
- dizziness; headache; tingling sensation
- slow heart rate
- hot flushes
- shortness of breath
- abdominal pain; abdominal bloating; constipation; indigestion; flatulence; frequent bowel movements; inflammation of the stomach; nausea; stomach discomfort; upset stomach
- acne; hives
- joint pains; back pain; leg cramps; muscle fatigue, spasms, or weakness; pain in hands and legs
- unusual weakness; feeling tired or unwell; swelling especially in the ankles (edema)
- elevation in certain laboratory blood tests of liver or muscle (CK) function
- weight gain

Side effects whose frequency is unknown (effects whose frequency has not been determined):

- myasthenia gravis (a disease causing generalized muscle weakness, including, in some cases, muscles used when breathing)
- ocular myasthenia (a disease causing eye muscle weakness)

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

Additionally, the following side effects have been reported in people taking Torez, or ezetimibe or atorvastatin tablets:

- allergic reactions, including swelling of the face, lips, tongue, and/or throat, that may cause difficulty in breathing or swallowing (which require immediate treatment)
- raised red rash, sometimes with target-shaped lesions
- liver problems
- cough
- heartburn
- decreased appetite; loss of appetite
- high blood pressure
- skin rash and itching; allergic reactions including rash and hives
- tendon injury
- gallstones or inflammation of the gallbladder (which may cause abdominal pain, nausea, vomiting)
- inflammation of the pancreas, often with severe abdominal pain
- reduction in blood cell counts, which may cause bruising/bleeding (thrombocytopenia)
- inflammation of the nasal passages; nosebleed
- neck pain; pain; chest pain; pain in the throat
- increases and decreases in blood sugar levels (if you have diabetes, you should continue to carefully monitor your blood sugar levels)
- nightmares
- numbness or tingling in the fingers and toes
- reduction of sensation to pain or touch
- change in sense of taste; dry mouth
- loss of memory
- ringing in the ears; hearing loss
- vomiting
- belching
- hair loss
- raised body temperature
- urine tests that are positive for white blood cells
- blurred vision; visual disturbances
- gynecomastia (breast enlargement in men and women)

Possible side effects reported while using other medicines of the statins group:

- sexual function difficulties
- depression

- breathing problems, including persistent cough and/or shortness of breath or fever
- diabetes. This is more likely if you have high blood levels of sugars and fats, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine
- muscle pain, tenderness, or weakness that is constant and particularly if, at the same time, you feel unwell or have a high fever that may not go away after stopping **Torez** (frequency unknown)

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 (<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>

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

5. HOW SHOULD TOREZ 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 **Torez** after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C and in a place protected from light.
- Do not dispose of medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION

What does Torez contain?

In addition to the active ingredients, **Torez** also contains:

Torez 10/10:

Lactose monohydrate; Calcium carbonate; Microcrystalline cellulose; Crospovidone; Croscarmellose sodium; White coating blend (Hypromellose, Titanium dioxide, Polyethylene glycol); Povidone 30; Magnesium stearate; Hydroxypropyl cellulose; Sodium lauryl sulfate; Polysorbate 80.

Torez 10/20:

Lactose monohydrate; Calcium carbonate; Microcrystalline cellulose; Crospovidone; Croscarmellose sodium; Magnesium stearate; White coating blend (Hypromellose, Titanium dioxide, Polyethylene glycol); Brown coating blend (Hypromellose, Titanium dioxide, talc, Macrogel/PEG 400, Iron oxide yellow, Iron oxide red, Iron oxide black); Hydroxypropyl cellulose; Povidone 30; Sodium lauryl sulfate; Polysorbate 80.

Torez 10/40:

Lactose monohydrate; Calcium carbonate; Microcrystalline cellulose; Crospovidone; Croscarmellose sodium; Magnesium stearate; Hydroxypropyl cellulose; White coating blend (Hypromellose, Titanium dioxide, Polyethylene glycol); Brown coating blend (Hypromellose, Titanium dioxide, talc, Macrogel/PEG 400, Iron oxide yellow, Iron oxide red, Iron oxide black); Povidone 30; Polysorbate 80; Sodium lauryl sulfate.

Torez 10/80:

Lactose monohydrate; Calcium carbonate; Microcrystalline cellulose; Crospovidone; White coating blend (Hypromellose, Titanium dioxide, Polyethylene glycol); Magnesium stearate; Croscarmellose sodium; Hydroxypropyl cellulose; Polysorbate 80; Povidone 30; Sodium lauryl sulfate.

What film-coated **Torez** tablets look like and the contents of the package:

Torez 10/10: Film-coated, round, biconvex, white to off-white tablets with a break line on one side.

Torez 10/20: Film-coated, round, biconvex, light brown tablets with a break line on one side.

Torez 10/40: Film-coated, capsule shape, biconvex, light brown tablets with a break line on one side.

Torez 10/80: Film-coated, oval shape, biconvex, white to off-white tablets with a break line on one side.

Torez is packaged in trays (blister) that are inserted into a carton package.

For **Torez 10/10**, there are package sizes of 14, 28, 30, 56 and 60 tablets.

For **Torez 10/20, 10/40, 10/80**, there are package sizes of 28, 30, 56 and 60 tablets.

Not all package sizes may be marketed.

Registration holder and address: Unipharm Ltd., P.O. Box 16545, Tel Aviv, 6116401.

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

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

Torez 10/10: 179 65 37663 99

Torez 10/20: 179 66 38154 99

Torez 10/40: 179 67 38155 99

Torez 10/80: 179 68 38156 99



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