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

The medicine is dispensed with a doctor's prescription only

Torva 10
Torva 20
Torva 40
Torva 80
Tablets

Composition:

Each tablet of **Torva 10** contains:
Atorvastatin (as calcium salt) 10 mg
Each tablet of **Torva 20** contains:
Atorvastatin (as calcium salt) 20 mg
Each tablet of **Torva 40** contains:
Atorvastatin (as calcium salt) 40 mg
Each tablet of **Torva 80** contains:
Atorvastatin (as calcium salt) 80 mg

For a list of the 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 to yours.

1. WHAT IS THE MEDICINE INTENDED FOR?

- To reduce blood fat levels (cholesterol and triglycerides) and increase HDL.
- To prevent cardiovascular diseases (e.g., myocardial infarction and/or stroke) in patients at high risk of a primary event.
- In patients with coronary heart disease, **Torva** reduces the risk of myocardial infarction, stroke, hospitalization due to heart failure, angina pectoris and/or need for catheterization.

Therapeutic group:

Statins – HMG-CoA reductase enzyme inhibitors.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (listed in section 6).
- You are suffering from active liver disease or when there is a prolonged increase in blood transaminase levels.
- You are pregnant, think you are pregnant or are planning to become pregnant.
- You are breastfeeding.
- You are taking cyclosporine, telaprevir (to treat hepatitis C) or a combination of the medicines tipranavir and ritonavir (to treat HIV).
- You are suffering from a skeletal muscle disease.

Special warnings regarding use of the medicine

Before treatment with Torva, tell the doctor if:

- You are suffering from muscle pains or weakness.
- You drink more than two glasses of alcohol a day.
- You are suffering from diabetes.
- You are suffering from thyroid problems.
- You are suffering from kidney problems.
- You suffered in the past from liver problems.

Children and adolescents

This medicine is usually not intended for children under 10 years of age and for girls who have not yet gotten their period.

Tests and follow-up

Before beginning treatment with **Torva**, it is recommended to perform a liver function test. It may be necessary to repeat these tests during the course of treatment with the medicine.

- Before any surgery (including dental), inform the doctor that you are taking this medicine.
- Statins may increase the risk of diabetes onset in patients who are in a risk group; blood sugar levels must be monitored in these patients.

Before starting treatment with the medicine, try to control excess cholesterol by appropriate diet.

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 which when combined with **Torva** increase its blood concentration and may increase the risk of muscle pain:
  Clarithromycin (antibiotic), fusidic acid, protease inhibitors to treat AIDS: tipranavir, ritonavir, lopinavir, saquinavir, darunavir, fosamprenavir, nelfinavir. Protease inhibitors for treatment of hepatitis C: glecaprevir, pibrentasvir, simeprevir, elbasvir, grazoprevir. Itraconazole (antifungal), cyclosporine, letermovir, gemfibrozil, cholesterol-lowering fibrates, niacin, colchicine (for gout).
- Medicines which when combined with **Torva** lower its blood concentration:
  Efavirenz, rifampin (antibiotic).
- Medicines whose blood concentrations increase when combined with atorvastatin:
  Digoxin (for the heart), contraceptive pills containing norethindrone and ethinylestradiol.
- Medicines that in combination with atorvastatin affect the activity of certain hormones in the body:
  Ketoconazole, spironolactone and cimetidine
- Do not take **Torva** together with the following medicines:
  Cyclosporine, telaprevir (for treatment of hepatitis C) or a combination of the medicines tipranavir and ritonavir (for treatment of HIV).

Use of the medicine and food

- The medicine can be taken with or without food.
- Do not eat grapefruit or drink grapefruit juice during the course of treatment with the preparation.
- Maintain a low-cholesterol diet while using the preparation.

Use of the medicine and alcohol

During the course of treatment with the medicine, do not drink more than two glasses of alcohol per day (see section 2 – subsection "Before treatment with **Torva**, tell the doctor if").

Pregnancy, breastfeeding and fertility

Do not use the medicine if you are pregnant, think you are pregnant, or are planning to become pregnant, or are breastfeeding. If you become pregnant during the course of treatment with the medicine, stop taking it immediately and refer to the doctor.

Important information about some of the ingredients of the medicine

This medicine contains lactose. If you have been told by the doctor that you suffer from an intolerance to certain sugars, consult the doctor before taking the medicine.

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 dosage and treatment regimen of the preparation.

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

Do not exceed the recommended dose. This medicine is not usually intended for children under 10 years of age and for girls who have not yet gotten their period.

Swallow the tablet whole with a little water. The tablet can be taken at any time of the day, preferably at a set time.

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 the doctor.

The dosage will be gradually reduced.

Note:

Wait at least two hours between taking this medicine and taking antacids.

Torva 10, Torva 20: If necessary, the tablet can be halved for immediate use.

Torva 40: Do not halve the tablet.

Torva 80: If necessary, the tablet can be halved for immediate use.

There is no information regarding crushing or chewing the tablet.

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 forgot to take this medicine at the required time, take a dose as soon as you remember, but never take a double dose!

Adhere to the treatment regimen as recommended by the doctor.

Do not take medicines in the dark! Check the label and 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 **Torva** 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.

Serious side effects:

Use of **Torva** may cause the following serious side effects, which usually disappear with dosage reduction or treatment discontinuation:

- **Muscle problems –** Use of **Torva** can cause serious muscle problems that may lead to kidney problems, including kidney failure. The risk of muscle problems appearing is greater when **Torva** is taken in combination with other medicines (see section "Medicines which when combined with **Torva** increase its blood concentration and may increase the risk of muscle pain").
- **Liver problems – Refer to the doctor immediately** if you develop symptoms of liver problems such as: sensation of tiredness or weakness, loss of appetite, pain in the upper abdomen, urine color becoming darker (amber color), yellowing of the skin and the whites of the eyes.

Refer to a doctor immediately if:

- You have muscle problems, such as weakness, tenderness, or pain that appeared without a clear reason, especially if accompanied by fever or you feel more tired than usual. This may be a sign of a rare muscle problem.
- You have muscle problems that do not go away even after the doctor has instructed you to stop taking the medicine. The doctor may refer you for further tests to determine the cause of the muscle problems.
- You develop an allergic reaction causing swelling of the face, lips, tongue and/or throat that may cause difficulties breathing or swallowing. Immediate treatment may be required.
- You suffer from nausea and vomiting.
- The color of urine becomes dark or brown.
- You feel more tired than usual.
- The color of the skin and whites of the eyes turns yellow.
- You suffer from abdominal pain.
- You suffer from an allergic skin reaction.

Common side effects – nasopharyngitis, joint stiffness, diarrhea, pain in the extremities, urinary tract infection, indigestion, nausea, muscle and joint pain, muscle spasms, fibromyalgia (myalgia, pain in the connective tissue and muscles), insomnia and pharyngolaryngeal pain.

Additional side effects:

General effects: tiredness, fever.

Gastrointestinal effects: abdominal discomfort, bloating, gas, hepatitis, cholestasis (a condition in which there is a blockage of bile flow within the liver, which can cause jaundice and damage to the liver).

Musculoskeletal effects: musculoskeletal pain, muscle weakness, neck pain, joint swelling, symptoms of lupus-like disease (including rash, joint disorders and effects on blood cells).

Changes in blood tests: increased transaminase level, changes in liver enzyme level, increased alkaline phosphatase level, increased creatine kinase level, increased blood sugar level (hyperglycemia).

Nervous system effects: nightmares.

Respiratory system effects: nosebleed.

Skin effects: urticaria.

Visual and auditory systems effects: blurred vision, tinnitus.

Urinary system effects: appearance of white blood cells in urine.

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.

Additionally, you can report to "Unipharm Ltd.".

5. HOW SHOULD THE MEDICINE BE STORED?

Store the medicine below 25°C and in a place protected from light.

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.

Do not dispose of medicines in wastewater or the waste bin. Consult a pharmacist regarding how to dispose of medicines that are no longer needed. These measures will help protect the environment.

6. FURTHER INFORMATION

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

Calcium carbonate, Lactose monohydrate, Microcrystalline cellulose, Hydroxypropyl cellulose, Carmellose sodium LS, Polysorbate 80, Magnesium stearate, Opadry white Y-1-7000.

The preparation contains lactose:

Torva 10: 40 mg lactose monohydrate.
Torva 20: 80 mg lactose monohydrate.
Torva 40: 160 mg lactose monohydrate.
Torva 80: 320 mg lactose monohydrate.

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

Torva is packaged in trays (blister) which are inserted into a carton package. Each pack contains 10, 20 or 30 tablets. Not all package sizes may be marketed.

Torva 10: a round, biconvex, white, film-coated tablet with a score line on one side.
Torva 20: a round, biconvex, white, film-coated tablet with a score line on one side.
Torva 40: an oval, biconvex, white, film-coated tablet.
Torva 80: an oval, biconvex, white, film-coated tablet with a score line on one side.

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

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

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

Torva 10: 132 08 30927 00
Torva 20: 132 09 30928 00
Torva 40: 132 10 30929 00
Torva 80: 167 21 36046 00

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unipharm ltd.

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