

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1866**  
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) 10 mg

Each tablet of **Torva 20** contains:

Atorvastatin (as calcium) 20 mg

Each tablet of **Torva 40** contains:

Atorvastatin (as calcium) 40 mg

Each tablet of **Torva 80** contains:

Atorvastatin (as calcium) 80 mg

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

**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 suffer from liver problems (severe liver failure or uncontrolled hepatic cirrhosis).
- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (listed in section 6 "Further information"). Stop using the medicine and seek medical assistance immediately if you experience signs of severe allergy, including:
  - swelling of the face, lips, tongue or throat.
  - difficulty breathing or swallowing.
  - faintness or dizziness.

- very rapid pulse.
- rash or severe itching of the skin.
- flu-like symptoms including fever, sore throat, cough, tiredness, and joint pain.

### Special warnings regarding use of the medicine

#### Before treatment with Torva, tell the doctor if:

- You suffer from unexplained muscle pains or weakness.
- You drink more than two glasses of alcohol a day.
- You suffer from diabetes.
- You suffer from thyroid problems.
- You suffer from kidney problems.
- You have had a stroke.
- You are pregnant or plan to become pregnant.
- You are breastfeeding or plan to breastfeed.
- You suffer or have suffered in the past from myasthenia (a disease associated with generalized weakness of muscles, including, in some cases, muscles used for breathing), or ocular myasthenia (a disease causing eye muscle weakness), as statins may sometimes aggravate the condition or lead to the onset of myasthenia (see section 4 "Side effects").

### 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 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 for the immune system (cyclosporin).
- Medicines for cholesterol (gemfibrozil).
- Medicines for infections (erythromycin, clarithromycin, itraconazole, ketoconazole, voriconazole, posaconazole, and rifampicin).
- Oral contraceptives.
- Medicines for heart failure (digoxin).
- Medicines for gout (colchicine).
- Niacin.
- Fibrates.
- Medicines for viruses, that treat HIV, AIDS or hepatitis C (antivirals):
  - tipranavir with ritonavir.
  - ledipasvir with sofosbuvir.
  - saquinavir with ritonavir.
  - elbasvir with grazoprevir.
  - nelfinavir.
  - glecaprevir with pibrentasvir.
  - simeprevir.
  - darunavir with ritonavir.

- fosamprenavir with ritonavir
- letermovir.
- lopinavir with ritonavir.
- fosamprenavir.

### Use of the medicine and food

- The medicine can be taken with or without a meal.
- Do not drink large amounts of grapefruit juice (more than one liter per day) during the course of treatment with the preparation.
- Maintain a low-cholesterol diet while using the preparation.

### Use of the medicine and alcohol consumption

During the course of treatment with the medicine, do not drink more than two glasses of alcohol per day (see section 2 "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, are planning to become pregnant, or are breastfeeding. If you become pregnant during the course of treatment with the medicine, stop taking it and immediately refer to the doctor since the medicine may cause harm to the unborn baby.

### 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.

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.

**Torva 10, 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. Do not take the dose if more than 12 hours have passed since you forgot the dose. In any case, **do not take a double dose.**

Adhere to the treatment regimen 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.

**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 serious side effects, including:

- **Muscle pain, tenderness, and muscle weakness (myopathy).** Muscle problems, including muscle breakdown, which may be serious in certain people and in rare cases, can cause kidney damage which can lead to death. **Refer to a doctor immediately if:**

- You experience signs of severe allergy, including:
  - swelling of the face, lips, tongue or throat.
  - difficulty breathing or swallowing.
  - faintness or dizziness.
  - very rapid pulse.
  - rash or severe itchiness of the skin.
  - flu-like symptoms including fever, sore throat, cough, tiredness, and joint pain.
- You are suffering from muscle pains, weakness and tenderness which began without a clear reason. Especially if they are accompanied with fever or if you feel more tired than usual.
- You are suffering from 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 additional tests to determine the cause of the muscle problems.

The chance of developing muscle problems increases if you:

- take certain other medicines during treatment with **Torva**.
- drink large amounts of grapefruit juice.
- are 65 years of age or older.
- suffer from uncontrolled thyroid problems (underactivity of the gland, hypothyroidism).
- suffer from kidney problems.
- are taking high dosages of **Torva**.

• **Liver problems – Refer to the doctor immediately** if you develop the following symptoms of liver problems:

- sensation of tiredness or weakness.
- nausea or vomiting.
- loss of appetite.
- pain in the upper abdomen.
- urine color becoming darker (amber color).
- yellowing of the skin and the whites of the eyes.

#### The most common side effects are:

nasal congestion, sore throat, runny nose, diarrhea, pain in the extremities, urinary tract

infection, nausea, muscle and joint pains, muscle spasms, stomach pains, insomnia.

#### Additional side effects:

General effects: malaise, fever.

Gastrointestinal effects: abdominal discomfort, bloating, flatulence, 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 phosphokinase 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.

**Side effects that have been reported after the preparation was marketed (the frequency can not be accurately estimated due to voluntary reporting by patients who used the preparation and there is no way of estimating the size of the relevant population):**

Gastrointestinal effects: pancreatitis.

General effects: tiredness.

Liver- and bile-related effects: liver failure that can be life-threatening.

Immune system effects: anaphylaxis (severe hypersensitivity reaction to a foreign agent).

Injuries: tendon rupture.

Musculoskeletal effects: muscle inflammation and rhabdomyolysis (breakdown of muscle cells).

Nervous system effects: dizziness, peripheral nerve damage, myasthenia gravis (a disease causing generalized weakness of muscles, including, in some cases, muscles used for breathing).

There were rare cases of cognitive impairment (e.g., memory loss, amnesia, memory impairment, confusion) associated with statin use.

The cognitive impairment was usually not serious and reversible upon discontinuation of statin use.

Psychiatric effects: depression.

Respiratory effects: interstitial lung disease.

Skin effects: localized edema, rash.

Visual system effects: ocular myasthenia (a disease causing eye muscle weakness).

Refer to the doctor if you experience weakness in the arms or legs that worsens after periods of activity, double vision or drooping of the eyelids, difficulty swallowing, or 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 "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> 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 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 the medicine below 25°C and in a place protected from light.

### 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-17000.

#### 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. For the 80 dose, there is also a package of 28 tablets. Not all package sizes may be marketed.

**Torva 10:** a round, biconvex, white, film-coated tablet with a break line on one side.

**Torva 20:** a round, biconvex, white, film-coated tablet with a break line on one side.

**Torva 40:** a round, biconvex, white, film-coated tablet.

**Torva 80:** an oval, biconvex, white, film-coated tablet with a break line on one side.

**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:

**Torva 10:** 132 08 30927 00

**Torva 20:** 132 09 30928 00

**Torva 40:** 132 10 30929 00

**Torva 80:** 167 21 36046 00