



Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

LITORVA® 10, 20, 40, 80 MG, TABLETS

Each tablet contains atorvastatin (as calcium) 10, 20, 40, or 80 mg respectively.
Inactive ingredients and allergens in the medicine - see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar to yours.

1. What is the medicine intended for?

- To reduce the blood lipid levels (cholesterol and triglycerides) and to increase HDL.
- To prevent cardiovascular diseases (e.g., myocardial infarction or stroke) in patients at high risk for a primary event.
- In patients with a coronary heart disease, **Litorva** reduces the risk of the occurrence of myocardial infarction, stroke, hospitalization due to heart failure, angina pectoris and/or the 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 disease (acute liver failure or decompensated cirrhosis)
- You are hypersensitive (allergic) to the active ingredient (atorvastatin) or to any of the other ingredients this medicine contains (see section 6).
Stop using this medicine and seek medical help immediately if you feel signs of acute allergy, such as:
 - swelling of the face, lips, tongue or throat
 - difficulties breathing or swallowing
 - fainting or dizziness
 - very fast heart beat
 - severe skin rash or itching
 - flu-like symptoms including fever, sore throat, cough, tiredness and joint pain

Special warnings regarding the use of the medicine

Before the treatment with Litorva, tell the doctor if:

- You suffer from unexplained muscle aches or weakness.
- You drink more than two glasses of alcohol daily.
- You suffer from diabetes.
- You suffer from thyroid problems.
- You suffer from kidney problems.
- You suffered from a stroke.
- You are pregnant or are planning to become pregnant.
- You are breastfeeding or are planning to breastfeed.
- You suffer or have suffered in the past from myasthenia (a disease accompanied by general muscle weakness, including in some cases muscles used when breathing), or from ocular myasthenia (a disease causing eye muscle weakness), since statins can sometimes worsen the condition or cause an outbreak of myasthenia (see section 4).

Children and adolescents

This medicine is usually not intended for children under 10 years of age and girls who have not yet started menstruating.

Tests and follow-up

Before starting treatment with **Litorva**, it is recommended to perform a liver function test.

These tests may need to be repeated during treatment with the medicine.

Before starting treatment with the medicine, try to control excess cholesterol with 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 (ciclosporin)
- medicines for cholesterol (gemfibrozil)
- medicines for infections (erythromycin, clarithromycin, itraconazole, ketoconazole, voriconazole, posaconazole and rifampin)
- contraceptive pills
- medicines for heart failure (digoxin)
- medicines for gout (colchicine)
- niacin
- fibrates
- medicines for viruses that treat HIV, AIDS or hepatitis C (antiviral medicines)
 - tipranavir in combination with ritonavir
 - ledipasvir in combination with sofosbuvir
 - saquinavir in combination with ritonavir
 - elbasvir in combination with grazoprevir
 - nelfinavir
 - glecaprevir in combination with pibrentasvir
 - simeprevir
 - darunavir in combination with ritonavir
 - fosamprenavir in combination with ritonavir
 - letermovir
 - lopinavir in combination 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 a liter per day) during treatment with the medicine.
- Be sure to maintain a low cholesterol diet while using the medicine.

Use of the medicine and alcohol consumption

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

Pregnancy, breastfeeding and fertility

Do not use the medicine if you are pregnant, think you may be pregnant or are planning to become pregnant or if you are breastfeeding.

If you become pregnant while using the medicine, stop taking it and refer immediately to the doctor as the medicine may harm the foetus.

Important information about some of the ingredients of this medicine

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

3. How to use the medicine?

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

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

Do not exceed the recommended dose.

Method of administration

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

Do not halve the tablet as there is no score line. There is no information about chewing/crushing the tablet.

If you have accidentally taken a higher dosage

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to take this medicine at the designated 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.

Continue with the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop taking this medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

Like any medicine, the use of **Litorva** 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:

The use of **Litorva** can cause occurrence of serious side effects, including:

- **Muscle pain, tenderness and weakness (myopathy).** Muscle problems, including muscle breakdown, might be severe in some people and rarely cause kidney damage which might lead to death.

Refer to a doctor immediately if:

- You feel signs of a severe allergy, including:
 - swelling of the face, lips, tongue or throat
 - difficulty breathing or swallowing
 - fainting or dizziness
 - very fast heartbeat
 - severe skin rash or itching
 - flu-like symptoms including fever, sore throat, cough, tiredness and joint pain.
- You suffer from muscle pain, weakness and tenderness that started with no clear reason. Especially if accompanied by fever or if you feel more tired than usual.
- You suffer from muscle problems that do not go away after the doctor told you to stop taking the medicine. The doctor may refer you to further tests to find the cause for these muscle problems.

The chances to develop muscle problems increase if you:

- take other certain medicines while treatment with Litorva
- drink large amounts of grapefruit juice
- are aged 65 or older
- suffer from uncontrolled thyroid gland problems (hypothyroidism)
- suffer from kidney problems

- take high doses of **Litorva**
- **Liver problems – contact a doctor immediately** if you develop these symptoms of liver problems:
 - feeling of tiredness or weakness
 - nausea or vomiting
 - loss of appetite
 - pain in the upper abdomen
 - the urine's color becomes 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 limbs, urinary tract infection, nausea, muscle and joint pain, muscle spasms, stomachache, insomnia.

Additional side effects:

General effects: feeling sick, fever.

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

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 levels, changes in liver enzyme levels, 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 the urine.

Side effects reported after marketing the medicine (the frequency cannot be estimated since the reports are voluntary from patients used this medicine and the population size cannot be estimated):

Gastrointestinal effects: pancreatitis

General effects: tiredness

Liver and bile related effects: hepatic failure which might be life threatening

Immune system effects: anaphylaxis (hypersensitivity reaction to a foreign body with high severity)

Injuries: tendon rupture

Musculoskeletal effects: myositis and rhabdomyolysis (muscle cells breakdown)

Nervous system effects: dizziness, peripheral nerve damage, myasthenia gravis (a disease causing general muscle weakness, including in some cases muscles used when breathing)

There have been rare cases of cognitive impairment (such as memory loss, amnesia, memory impairment, confusion) associated with the use of statins. The cognitive impairment usually was not severe and reversible upon cessation of statin use.

Psychiatric effects: depression

Respiratory system effects: interstitial lung disease

Skin effects: local edema, rash

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

Contact a doctor if you feel 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 this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking the link " דיווח על תופעות לוואי " עקב טיפול תרופתי found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants 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 (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store in the original package, not above 25°C.

6. Additional information

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

Starch pregelatinized, lactose monohydrate, crospovidone, hydroxypropylcellulose, magnesium stearate, hypromellose, silica colloidal anhydrous, titanium dioxide (E-171), macrogol, carnauba wax.

What the medicine looks like and what the package contains:

Litorva 10, 20, 40: White tablets, round and coated with 10, 20 and 40 imprinted respectively.

Litorva 80: White tablets, oval and coated.

Approved package sizes: 2, 10, 30 tablets. Not all package sizes may be marketed.

Manufacturer name and address:

Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel

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Drug registration number at the national drug registry of the Ministry of Health:

Litorva 10: 145-31-33305

Litorva 20: 145-32-33307

Litorva 40: 145-30-33287

Litorva 80: 148-02-33632

Registration holder: Dexcel Pharma Technologies Ltd., 10 Hakidma St., Yokneam 2069200, Israel