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) at a dosage of 10, 20, 40, or 80 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.

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 are hypersensitive (allergic) to the active ingredient (atorvastatin) or to any of the other ingredients this medicine contains (see section 6).
- you suffer from active liver disease or if you have persistent elevation of blood transaminase levels.
- you are pregnant, think you may be pregnant or are planning to become pregnant.
- you are breastfeeding.
- you are taking cyclosporine, telaprevir (for the treatment of hepatitis C) or a combination of the medicines tipranavir and ritonavir (for the treatment of the AIDS virus).
- you suffer from a disease of the skeletal muscles.

Special warnings regarding the use of the medicine
Before the treatment with Litorva, tell the doctor if:

- you suffer from 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 suffer from liver problems.

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.
Inform the doctor that you are taking the medicine before any kind of surgery (including dental surgery).
Statins may increase the risk of diabetes in patients who are in a risk group, these patients require monitoring of blood sugar level.
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 that in combination with **Litorva** increase its blood concentration and may increase the risk of muscle pain:
  Clarithromycin (antibiotic), fusidic acid, protease inhibitors for the treatment of AIDS: tipranavir, ritonavir, lopinavir, saquinavir, darunavir, fosamprenavir, nelfinavir; protease inhibitors for the treatment of hepatitis C: glecaprevir, pibrentasvir, simeprevir, elbasvir, ledipasvir and sofosbuvir, grazoprevir; itraconazole (antifungal), cyclosporine, letermovir, gemfibrozil, cholesterol-lowering fibrates, niacin, colchicine (for gout).
- Medicines that in combination with **Litorva** reduce its blood concentration:
  Efavirenz, rifampin (antibiotic)
- Medicines whose blood concentration rises when administered in combination with atorvastatin:
  Digoxin (for the heart), contraceptive pills that contain 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 **Litorva** together with the following medicines: cyclosporine, telaprevir (for the treatment of hepatitis C) or a combination of the medicines tipranavir and ritonavir (for the treatment of the AIDS virus).

Use of this 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 this medicine and alcohol consumption
During treatment with the medicine do not drink more than two glasses of alcohol per day (see 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.

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 certains sugars, consult the doctor before taking the medicine.

3. How to use this 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.
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 the occurrence of the following serious side effects which usually disappear upon dosage reduction or treatment discontinuation:

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

Refer immediately to the doctor if:

- you suffer from muscle problems such as weakness, tenderness or pain that began without a clear reason, especially if accompanied by fever or if you feel more tired than usual. This may be a sign of a rare muscle problem.
- you suffer from muscle problems that do not disappear even after the doctor has instructed you to stop taking the medicine. The doctor may refer you for additional tests to clarify the source of the muscle problems.
- you develop an allergic reaction that causes swelling of the face, lips, tongue and/or throat that may cause breathing or swallowing difficulties. Immediate medical treatment may be necessary.
- you suffer from nausea or vomiting.
- the urine color 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.
- an alleric reaction appears on the skin.

Common side effects (effects that appear in 1-10 out of 100 users)**:** nasopharyngitis, joint stiffness, diarrhea, pain in the limbs, urinary tract infection, indigestion, nausea, muscle and joint pain, muscle spasms, fibromyalgia (myalgia, connective tissue and muscle pain), insomnia and pharyngolaryngeal pain.

Additional side effects:
General effects: tiredness, 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 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 the urine.

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health via the link "דיווח על תופעות לוואי עקב טיפול תרופתי" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following 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 התפוגה) 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, this 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's name and address:
Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel

Revised in April 2022 according to MOH guidelines

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.
1 Dexcel St., Or Akiva 3060000, Israel