

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by it

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

The medicine is dispensed with a doctor's prescription only

Lipnanor Capsules

Each capsule contains:
Ciprofibrate 100 mg.

Inactive ingredients and allergens in the preparation - see section 6 and the "Important information about some ingredients of the medicine" section.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

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

This medicine is not intended for infants and children under 12 years of age.

1. What is the medicine intended for?

The medicine is intended for lowering blood cholesterol and triglyceride levels in cases where an appropriate diet is not effective.

Therapeutic class: fibrates.

2. Before using the medicine:

❗ Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or any of the additional components the medicine contains (for a list of inactive ingredients see section 6). Signs of allergy include: rash, problems swallowing or breathing, swelling of the lips, face, throat and/or tongue.
- You are pregnant, planning to become pregnant or breastfeeding.
- You are suffering from a severe impairment in kidney or liver function.
- You are taking another medicine of the Fibrates family (such as: clofibrate, bezafibrate, fenofibrate or gemfibrozil) for treatment of high levels of lipids in the blood.

Special warnings regarding the use of the medicine:

❗ Before treatment with Lipnanor, inform the doctor if:

- You are suffering from sensitivity, weakness or muscle pains.
- You have liver or kidney problems.
- You are suffering from underactivity of the thyroid.
- You are over 70 years old.
- You or a member of your family have had muscle problems in the past.

❗ Tests and follow-up:

During treatment with this medicine, lipids levels in the blood and liver functions should be tested.

Blood tests

- Taking a medicine that contains the active ingredient ciprofibrate may affect the outcome of certain blood tests. During treatment with this medicine, the doctor may perform blood tests in order to follow the liver function.
- If you had blood tests while being treated with this medicine, it is important to notify the doctor/nurse that you are taking Lipnanor.

❗ Drug-drug interactions:

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

Especially if you are taking:

- Statins - other medicines for lowering lipid blood levels such as: simvastatin, atorvastatin, pravastatin, fluvastatin and rosuvastatin.
- Blood thinning medicines such as warfarin.
- Medicines for diabetes, such as insulin or metformin.
- Medicines that contain estrogens such as contraceptive pills, hormone replacement therapy.

❗ Use of the medicine and food:

The medicine should be taken with food.

❗ Use of the medicine and alcohol consumption:

Alcohol consumption should be limited during treatment with this medicine. Excessive alcohol consumption may aggravate muscle pains (a side effect).

❗ Pregnancy, breastfeeding and fertility:

Do not use Lipnanor if you are pregnant, planning to become pregnant, breastfeeding or planning to

breastfeed, as a small amount of ciprofibrate may pass through breastmilk.

❗ Driving and operating machinery:

If you are suffering from dizziness, drowsiness and/or tiredness while taking this medicine, you should avoid driving or operating dangerous machinery.

❗ Important information about some ingredients of the medicine:

This preparation contains lactose. If you are suffering from intolerance to certain sugars, consult a doctor before starting to use this 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 how to use the preparation.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is: one capsule per day (for patients with kidney function problems, the medicine should be taken less frequently - take one capsule every other day).

Do not exceed the recommended dose.

The medicine should be taken with food.

The capsule may be opened and its entire content swallowed.

If you took an overdose or if a child swallowed this medicine by mistake, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.

If you have forgotten to take this medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult a doctor.

How can you contribute to the success of the treatment?

A low-fat diet should be followed, combined with physical exercise and weight loss to lower lipid blood levels.

Follow 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, as your illness may worsen.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine.

Wear glasses if you need them.

If you have any other questions regarding

use of the medicine, consult the doctor or the pharmacist.

4. Side effects:

As with any medicine, using Lipnanor may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Stop using this medicine and refer to a doctor immediately if:

- You experience muscle problems, such as cramps, pains or tenderness. These may lead to kidney failure.

Tell the doctor as soon as possible if:

- An allergic reaction appears. The signs may include: rash (accompanied by itching and bumps), itching and hypersensitivity to sunlight.
- You develop pneumonia that causes breathing difficulties, cough and fever.
- You develop scarring in the lungs that causes shortness of breath.
- Liver problems occur, which may cause a yellowish tinge in the skin and/or whites of the eyes (jaundice).
- You develop severe right epigastric abdominal pains, which may radiate to the back and be accompanied by nausea, vomiting and fever. This may be caused by biliary colic or gallbladder stones.

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

- Hair loss, balding.
- Headaches, balance problems.
- Dizziness, tiredness, drowsiness.
- Nausea, vomiting.
- Diarrhea, digestive disturbances, abdominal pains.
- Myalgia (muscle pain).

Side effects with unknown frequency:

- Impotence.
- Increased tendency for bruising, which may be due to blood cells disorders (decrease in platelets).
- Muscle weakness, cramps, stiffness, spasms.
- Muscle inflammation.

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 your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link:
<https://sideeffects.health.gov.il/>

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (Exp) appearing on the package. The expiry date refers to the last day of that month.

Store at a temperature not exceeding 25°C. Store in a cool and dry place.

Store in the original package.

6. Additional information:

In addition to the active ingredient the medicine also contains:

Lactose, maize starch, gelatin, titanium dioxide, yellow iron oxide, black iron oxide

What does the medicine look like and what are the contents of the package?

Each Lipnanor capsule contains white powder and consists of opaque cream-colored body and an opaque green cap. Each package contains 1, 2, 3, 6 or 10 blisters and each blister contains 10 capsules. Not all package sizes may be marketed.

Manufacturer/license holder and address:

CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi.

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