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

**The medicine is dispensed with a doctor's prescription only**

# Lipanor 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 case 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 an allergic reaction include: rash, swallowing or breathing problems, swelling of the lips, face, throat and/or tongue.
- You have used ciprofibrate (or similar substances) in the past and your skin reacted badly to sunlight.
- 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 Lipanor, inform the doctor if:**

- You are suffering from muscle tenderness, weakness or pain.
  The risk of muscle problems may be increased if you have any of the following risk factors:
  - Kidney problems or a reduced amount of protein (albumin) in the blood, such as when a certain disorder affects the kidneys (nephrotic syndrome)
  - Liver problems
  - Underactive thyroid gland
  - Excessive alcohol consumption
  - You are over 70 years old
  - You or a member of your family has had muscle problems in the past
  - History of muscle toxicity with another fibrate

**Tests and follow-up:**

Blood tests

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

**Drug interactions:**

**If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional 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.
- Oral blood thinning medicines such as warfarin.
- Oral medicines for the treatment of diabetes such as metformin.
- Medicines that contain estrogens such as contraceptive pills, hormone replacement therapy.
- Medicines for treatment of epilepsy such as phenytoin.
- Other fibrates

Taking cholestyramine or colestipol (other medicines for lowering cholesterol) together with Lipanor may affect the activity of Lipanor. Therefore, these medicines should be taken separately from one another.

**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. Excessive alcohol consumption may increase the side effect of muscle pain.

**Pregnancy, breastfeeding and fertility:**

Do not use Lipanor if you are pregnant, planning to become pregnant, breastfeeding or planning to breastfeed.

**Driving and operating machinery:**

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

**Important information about some ingredients of the medicine:**

The 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 generally accepted dosage is: one capsule per day (for patients who suffer from kidney function problems, reduce the frequency of taking the medicine – 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, refer to the doctor or a hospital emergency room immediately and take the package of the medicine with you.

**If you forgot to take this medicine** at the required time, take it as soon as you remember, unless it is time to take the next dose. Do not take a double dose in order to compensate for a forgotten dose.

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 a medicine. Wear glasses if you need them.**

**If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.**

## 4. Side effects:

As with any medicine, using Lipanor 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.

**Discontinue treatment and contact a doctor immediately if:**

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

**Contact the doctor as soon as possible if:**

- An allergic reaction appears. The signs include: rash (accompanied by itching and bumps), itching and hypersensitivity to sunlight.
- Shortness of breath. Some cases of lung inflammation (pneumonitis) or proliferation of connective tissue in the lung (lung fibrosis) have been reported.
- Liver problems occur, which may cause a yellow tinge in the skin and/or whites of the eyes (jaundice).
- Severe abdominal pain occurs (right side of the upper abdomen), which may radiate to the back and be accompanied by nausea, vomiting and fever. This side effect may be caused by biliary colic or gallbladder stones.

**Additional side effects**

**Rare side effects – effects that occur in 1-10 users out of 10,000:**

- Dizziness, fatigue, sleepiness.

**Side effects with unknown frequency:**

- Impotence.
- Hair loss, balding.
- Increased tendency for bruising, which may be due to blood cell disorders (decrease in platelets).
- Decrease in white blood cells. This effect increases the risk of infections.
- Headaches, problems with balance.
- Nausea, vomiting.
- Diarrhea, indigestion, stomach pain.

**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 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.

Do not store at a temperature that exceeds 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 Lipanor capsule contains white powder and consists of an opaque cream-colored body and an opaque green cap. Each package contains 1, 2, 3, 6, 10 blisters and each blister contains 10 capsules.

Not all package sizes may be marketed.

**Name and address of the manufacturer/ marketing authorization holder:** CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi.

This leaflet was revised in 05/2024 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 1055628758