**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

Dispensing this medicine requires a doctor's prescription

# Chenodeoxycholic acid Leadiant

Hard capsules

**Active ingredient:** Each capsule contains 250 mg chenodeoxycholic acid**.**

For a list of inactive ingredients and allergens see section 6: 'Additional information'.

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

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

## 1. What is this medicine intended for?

This medicine is intended for treating inborn problems producing primary bile acids because the enzyme sterol 27 hydroxylase is missing (an illness called cerebrotendinous xanthomatosis [CTX]. This medicine is intended for treating infants from one month old, children and adolescents up to 18 years old, and adults.

**Therapeutic group:** digestive tract and metabolism - bile treatments - bile acid medication.

**About chenodeoxycholic acid**

Chenodeoxycholic acid Leadiant capsules contain a substance called chenodeoxycholic acid. Normally, this substance is made from cholesterol in the liver. It is a component of bile, a fluid which helps in the digestion of fat and vitamins from food. People with a rare condition known as cerebrotendinous xanthomatosis (CTX) cannot produce chenodeoxycholic acid and this causes a buildup of fatty deposits in various areas of the body. These deposits can cause damage to the affected areas.

Chenodeoxycholic acid Leadiant capsules can be used from the age of one month and patients with CTX will require treatment for the rest of their lives.

## 2. Before using this medicine

**Do not take this medicine if:**

- you are sensitive (allergic) to chenodeoxycholic acid or to any of the other ingredients that this medicine contains (listed in Section 6).

**Special warnings about using this medicine**

Chenodeoxycholic acid Leadiant should be used under medical supervision. During your treatment, your doctor will refer you to blood and urine tests to monitor your response to this medicine, and adjust your dose if necessary. More frequent tests may be needed if you are growing fast, if you are ill (if you have e.g. liver problems), or if you are pregnant. Your doctor will advise you if for any reason you have to stop treatment with chenodeoxycholic acid Leadiant.

**Babies (less than one month of age)**

The safety and efficacy of Chenodeoxycholic acid Leadiant has not been studied in babies less than one month of age.

## Drug Interactions

**If you are taking, have recently taken or might take other medicines, including nonprescription medications and nutritional supplements, tell your doctor or pharmacist.**

The following medicines may affect the levels of chenodeoxycholic acid:

- cyclosporine and sirolimus (medicines used to suppress the immune system)
- phenobarbital (a medicine for treating epilepsy)

If your doctor considers it necessary for you to take ciclosporin, sirolimus or phenobarbital they will closely monitor the results of your blood and urine tests and adjust the dose of Chenodeoxycholic acid Leadiant if necessary

Oral contraceptives may affect the way in which chenodeoxycholic acid works making it less effective. Taking oral contraceptives is not recommended during treatment with Chenodeoxycholic acid Leadiant. Please discuss suitable contraceptive methods with your doctor.

The following medicines may reduce the effect of Chenodeoxycholic acid Leadiant:

- cholestyramine, colestipol (also called bile acid sequestrants)
- medicines to treat heartburn (antacids) containing aluminium hydroxide and/or smectite (aluminium oxide)

If you have to take cholestyramine, then take Chenodeoxycholic acid Leadiant either one hour before cholestyramine or 4-6 hours after.

For colestipol or heartburn medicines, take them either 2 hours before or 2 hours after taking Chenodeoxycholic acid Leadiant.

Talk to your doctor if you are taking any of these medicines.

**Using this medicine and food**

Swallow the medicine with water, with or without food.

**Pregnancy and breastfeeding**

Pregnancy

It is not recommended to take Chenodeoxycholic acid Leadiant during pregnancy. There might be a risk to your unborn baby. If you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Contraception in females

Women who could become pregnant should use an effective contraceptive method while on Chenodeoxycholic acid Leadiant. Oral contraceptives are not recommended (see 'Drug Interactions'). Please discuss suitable contraceptive methods with your doctor.

Breast-feeding

It is not known if Chenodeoxycholic acid Leadiant passes into breast milk. Tell your doctor if you are breastfeeding or plan to breast-feed. Your doctor will then help you decide whether to stop breast-feeding, or whether to stop taking Chenodeoxycholic acid Leadiant, considering the benefit of breast-feeding the baby and the benefit of Chenodeoxycholic acid Leadiant to the mother.

**Driving and using machines**

Chenodeoxycholic acid Leadiant is not expected to affect your ability to drive or operate machines.

**3. How to use this medicine?**

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

The usual starting dose in adults is one 250 mg capsule three times a day. The maximum dose is one 250 mg capsule four times a day. Swallow the capsules whole with water at approximately the same time each day. The capsules can be taken with or without food. Your doctor may decide to increase your dose depending on how your body responds to treatment. Your doctor will tell you how many capsules you need to take, and when you should take them.

**Use in children and adolescents (aged one month to 18 years)**

In babies, children and adolescents, the dose will be calculated based on the child’s weight. The starting dose will be calculated at 5 mg per kg body weight per day. The maximum dose for children is 15 mg per kg per day. The doctor will decide how many times and when your child should receive the dose to make up the total dose for the day. The doctor may change the dose depending on how your child responds to treatment.

**Do not exceed the recommended dose.**

For babies, children, and those who cannot swallow capsules and/or need to take a dose that is lower than 250 mg, a capsule may be opened and the contents mixed with 8.4% sodium bicarbonate solution. The active substance will be dissolved in the sodium bicarbonate solution but not all the contents of the capsule will be dissolved so it will look like a mixture. The mixture will be prepared and provided to you by your pharmacy. The mixture should be provided in a glass bottle and can be kept for up to 7 days. Do not refrigerate or freeze the mixture. Your doctor or pharmacist will give you instructions on how much and how often your child needs to take the mixture. The mixture contains sodium, tell your doctor if you are on a controlled sodium diet.

**If you take more Chenodeoxycholic acid Leadiant than you should**

Chenodeoxycholic acid Leadiant is not expected to cause serious side effects. Ask your doctor for advice if you or your child has taken more than the amount prescribed.

**If you forget to take Chenodeoxycholic acid Leadiant**

Skip the missed dose and take your next dose when you would normally take it. Do not take a double dose to make up for a forgotten dose. Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor or pharmacist.

**If you stop taking Chenodeoxycholic acid Leadiant**

This medicine is for long-term use. If you stop taking this medicine your symptoms may get worse.

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

If you have any further questions about using this medicine, consult your doctor or pharmacist.

## 4. Side effects

Like all medicines, this medicine may cause side effects in some people. Do not be alarmed by this list of side effects. You may not experience any of them.

**Side effects of unknown frequency (frequency cannot be estimated from available data)**

- constipation
- liver problems

**Reporting side effects**

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

https://sideeffects.health.gov.il

## 5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use this medicine after the expiry date (exp. date) which is stated on the package and label after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Additional information

**In addition to the active ingredient this medicine also contains:**

Capsule content:

maize starch, magnesium stearate, silica colloidal anhydrous, water.

Capsule shell:

gelatin, titanium dioxide (E 171), quinoline yellow (E 104), erythrosine (E 127).

**What the medicine looks like and contents of the pack:**

Chenodeoxycholic acid Leadiant is provided as hard capsules. The capsules have a yellow body and an orange cap which contains a white compressed powder.

Chenodeoxycholic acid Leadiant is available in blister packs containing 100 hard capsules.

**Registration holder:** MBI Pharma, P.O Box 5061, Kadima, Israel.

**Manufacturer:**

Pharmaloop S.L. Spain

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**Registration number of the medicine in the Ministry of Health's National Drug Registry: 159-45-35040-00**