

PACKAGE LEAFLET: INFORMATION FOR THE USER

LIPOFEN SR

250 mg CAPSULE, HARD

FENOFIBRATE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What LIPOFEN SR tablets is and what it is used for
2. Before you take LIPOFEN SR
3. How to take use LIPOFEN SR
4. Possible side effects
5. How to store LIPOFEN SR
6. Further information

1. WHAT LIPOFEN SR IS AND WHAT IT IS USED FOR

One LIPOFEN SR capsule contains 250 mg of fenofibrate.

LIPOFEN SR belongs to the group of medicines known as fibrates. These medicines are used to lower levels of fats (lipids) in the blood (eg. Fats called triglycerides).

LIPOFEN SR is used for lowering the blood fat levels, in addition to eating a proper diet (such as a low-fat diet) and other methods, which exclude the use of medicines, such as exercise and weight loss.

LIPOFEN SR can be used with other drugs (statins) in cases when the level of fat in the blood cannot be controlled only with statins.

It can also increase the amount of "good" cholesterol, called high density lipoprotein (HDL). It is necessary to continue a low-fat diet during the treatment.

2. BEFORE YOU TAKE LIPOFEN SR

Do not take LIPOFEN SR

- If you are allergic (hypersensitive) to fenofibrate or any of the other ingredients;
- if you have liver, kidney or gallbladder disease;
- if sunlight or ultraviolet rays have caused an allergic reaction or skin damage during the period when you were taking fibrates or anti-inflammatory medicine ketoprofen;
- if you are pregnant, breastfeeding or planning to become pregnant;
- if you suffer from pancreatitis (inflammation of the pancreas accompanied by abdominal pain), except in cases where it is caused by high levels of fat in the blood (hypertriglyceridemia).

Take special care with LIPOFEN SR, so you must tell the doctor if you

- Have an underactive thyroid
- drink alcohol
- are over 70 years old
- have had or have a family member with a history of hereditary muscular disorders
- are already taking a fibrate or a statin
- have poorly controlled diabetes mellitus (type II)
- have nephrotic syndrome
- have a condition which effects the amount of protein in the blood (dysproteinemia)
- have obstructive liver disease
- have kidney problems

(Some of the above mentioned conditions may lead to the emergence of high levels of fat in your blood and should be adjusted before starting treatment with fenofibrate.)

Your doctor may require blood and urine test results to check whether LIPOFEN SR acts appropriately, as well as whether your kidneys, muscles and liver are working as they should.

Important advices about the effect on the muscles:

Immediately contact your doctor if you experience unexplained muscle pain, tenderness and weakness. In rare cases, there is a risk of problems with muscles that can be serious, including muscle breakdown which can cause kidney damage. Your doctor may conduct blood tests to check the condition of your muscles before and after starting treatment.

The risk of muscle breakdown is higher in certain patients.

Tell your doctor if any of the following applies to you:

- You have any problems with kidneys;
- Your thyroid gland does not work as it should;
- You often drink large amounts of alcohol;
- If you have had problems with muscles during treatment with medicines for lowering cholesterol levels, which are called "statins" (eg. Simvastatin, atorvastatin, pravastatin, fluvastatin or rosuvastatin) or fibrates (such as ciprofibrate, bezafibrate or gemfibrozil);
- You or a close member of your family have a hereditary muscle disorder.

The risk of muscle problems can be greater if the LIPOFEN SR is taken with medicines to lower cholesterol levels called 'statins' (eg, simvastatin, atorvastatin, pravastatin, rosuvastatin, fluvastatin). Tell your doctor if you are taking any of these medicines.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

It is especially important that your doctor knows if you are already taking:
Anticoagulant for thinning the blood (eg. Warfarin);
Other medicines that control the levels of lipids (fats) in the blood (eg, drugs known as "statins" or "fibrates").
Taking a "statin" (eg, simvastatin, atorvastatin) at the same time as LIPOFEN SR can increase the risk of muscle problems;
Ciclosporin (used to suppress the immune system).

Taking LIPOFEN SR with food and drink

It is important that you take the capsules with food, otherwise the medicine will not work as well if your stomach is empty.

Pregnancy and breastfeeding

The use of LIPOFEN SR is not recommended during pregnancy and breastfeeding.

Important information about some of the ingredients in LIPOFEN SR

Lipophile SR contains coloring substance "sunset yellow" (E110) which may cause allergic reactions.

3. HOW TO TAKE LIPOFEN SR

The usual dose for adults is one LIPOFEN SR capsule per day, taken with a meal. Swallow a capsule with a glass of water.

LIPOFEN SR is not recommended for use in children under 18 years of age.

If you take more LIPOFEN SR than you should

If you take more LIPOFEN SR than you should immediately talk to your doctor or pharmacist.

If you forget to take LIPOFEN SR

Do not take a double dose to make up for a forgotten dose.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, LIPOFEN SR can cause side effects, although not everybody gets them.

side effects are classified as follows:

very common (affects 1 or more out of 10 patients) ;

common (affects 1 or more out of 100 , but less than 1 in 10 patients) ;

uncommon (affects 1 or more out of 1000 , but less than 1 in 100 patients) ;

rare (affects 1 or more per 10 000 , but less than 1 in 1000 patients) ;

very rare (affects less than 1 in 10,000 patients) ;

Common:

- Abdominal pain, nausea, diarrhea and wind (flatulence);
- Reactions such as rash, itching, red spots on the skin or increased sensitivity to sunlight, artificial tanning lamps and tanning;
- Headache, fatigue, dizziness.

Uncommon:

- Pancreatitis (inflammation of the pancreas which causes abdominal pain);
- Blood clots in the lungs causing chest pain and shortness of breath (pulmonary embolism);
- Blood clots in the leg, that cause pain, redness or swelling (deep vein thrombosis);
- Gallstones.

Rare:

- Increased levels of various liver enzymes in the blood;
- Slight rise in substances excreted by the kidneys (urea and creatinine);
- Decreased sex drive;
- Hair loss;
- Muscle pain, sore muscles, muscle cramps and weakness;
- Reduced hemoglobin (pigment in the blood which binds oxygen), and decreased white blood cell count

Very rare:

- Hepatitis (inflammation of the liver), symptoms that may be associated with mild jaundice (yellowing of the skin and whites of the eyes), abdominal pain and itching;
- Muscle breakdown;
- Chronic disease of the lung tissue.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE LIPOFEN SR

Keep out of the reach and sight of children.

Do not store above 30 °C.

Do not use LIPOFEN SR after the expiry date which is stated on the label.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What LIPOFEN SR contains

The active substance is fenofibrate. Each capsule contains 250 mg of fenofibrate.

The other ingredients are:

- The neutral microgranules (size 30) (sugar spheres)
- Basic butylated methacrylate copolymer (Eudragit E 100)
- Methacrylic acid • methyl methacrylate copolymer (1: 1) (Eudragit L 100)
- Talc
- Hard gelatin capsules *

* Light-orange opaque caps / orange translucent body. One hard gelatin capsule contains: sunset yellow FCF-FD & C Yellow (E110) and titanium dioxide (E171) as coloring agents and gelatin.

What LIPOFEN SR looks like and contents of the pack

LIPOFEN SR 250 mg capsules are hard gelatin capsules with bright-orange opaque caps and orange transparent body. Capsule`s content consists of spherical microgranules off-white to cream color.

LIPOFEN SR is packed in PVC-Al blister with 30 capsules.
(30 capsules / 2 blisters /1 box)

Regime of dispensing

The medicine is issued on prescription.

Manufacturer***Manufacturer***

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Ümraniye 34768 İstanbul Türkiye

Manufacturer of the medicinal product

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