

PACKAGE LEAFLET: INFORMATION FOR THE USER

LIPANTIL SUPRA® 145MG FILM-COATED TABLETS (fenofibrate)

Your medicine is available using the above name but will be referred to as Lipantil Supra throughout this leaflet.

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 or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

- What Lipantil Supra is and what it is used for
- What you need to know before you take Lipantil Supra
- How to take Lipantil Supra
- Possible side effects
- How to store Lipantil Supra
- Contents of the pack and other information

1. What Lipantil Supra is and what it is used for

Lipantil Supra belongs to a group of medicines, commonly known as fibrates. These medicines are used to lower the level of fats (lipids) in the blood. For example, the fats known as triglycerides.

Lipantil Supra is used, alongside a low fat diet and other non-medical treatments such as exercise and weight loss, to lower levels of fats in the blood.

Lipantil Supra can be used in addition to other medicines (statins) in some circumstances when levels of fats in the blood are not controlled with a statin alone.

2. What you need to know before you take Lipantil Supra

Do not take Lipantil Supra if:

- you are allergic to fenofibrate or any of the other ingredients of this medicine (listed in Section 6: Contents of the pack and other information)
- you are allergic to peanut or arachis oil or soya lecithin or related products
- while taking other medicines, you have had an allergic reaction or skin damage from sunlight or UV light (these medicines include other fibrates and an anti-inflammatory medicine called ('ketoprofen')
- have severe liver, kidney or gallbladder problems
- you have pancreatitis (an inflamed pancreas which causes abdominal pain) which is not caused by high levels of fat in the blood

Do not take Lipantil Supra if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Lipantil Supra.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Lipantil Supra if:

- you have any liver or kidney problems
- you may have an inflamed liver (hepatitis) – signs include yellowing of the skin and the whites of the eyes (jaundice), an increase in liver enzymes (shown in blood tests), stomach pain and itching
- you have an under-active thyroid gland (hypothyroidism)

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Lipantil Supra.

Effects on muscles

Stop taking Lipantil Supra and see a doctor straight away if you get unexplained cramps or painful, tender or weak muscles while taking this medicine.

- This is because this medicine may cause muscle problems, which may be serious.
- These problems are rare but include muscle inflammation and breakdown. This can cause kidney damage or even death.

Your doctor may do a blood test to check your muscles before and after starting treatment.

The risk of muscle breakdown is higher in some patients. Tell your doctor if:

- you are over 70 years old
- you have kidney problems
- you have thyroid problems
- you or a close family member has muscle problem which runs in the family
- you drink large amounts of alcohol
- you are taking medicines called statins to lower cholesterol such as simvastatin, atorvastatin, pravastatin, rosuvastatin or fluvastatin
- you have ever had muscle problems during treatment with statins or fibrates such as fenofibrate, bezafibrate or gemfibrozil.

If any of the above apply to you (or you are not sure), talk to your doctor before taking Lipantil Supra.

Other medicines and Lipantil Supra

Tell your doctor if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- anti-coagulants to thin your blood (such as warfarin)
- other medicines to control fat levels in the blood (such as, statins or fibrates). Taking a statin at the same time as Lipantil Supra may increase the risk of muscle problems
- a particular class of medicines to treat diabetes (such as rosiglitazone or pioglitazone)
- cyclosporin (an immunosuppressant)

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Lipantil Supra.

Lipantil Supra with food, drink and alcohol

The tablet should be taken with or without food, at any time of the day.

Pregnancy, breast-feeding and fertility

- Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby. As there is not enough experience with use of Lipantil Supra during pregnancy, you should use Lipantil Supra only if your doctor considers it absolutely necessary.
- It is not known, whether the active substance in Lipantil Supra passes into breast-milk. Therefore, you should not use Lipantil Supra if you are breast-feeding or planning to breastfeed your baby.

Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

This medicine will not affect you being able to drive or use tools or machines.

Lipantil Supra contains lactose and sucrose (types of sugar)

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Lipantil Supra contains soya oil

If you are allergic to peanut or soya, do not use this medicinal product.

3. How to take Lipantil Supra

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Swallow the tablet with a glass of water.
- Do not crush or chew the tablet.

How much to take

The recommended dose is one tablet a day. If you are currently taking one capsule of Lipantil Micro 200mg or one tablet of Lipantil Supra 160mg, you can change to one tablet of Lipantil Supra 145mg.

People with kidney problems

If you have kidney problems, your doctor may tell you to take a lower dose. Ask your doctor or pharmacist about this.

Use in children and adolescents

The use of Lipantil Supra 145mg is not recommended under 18 years.

If you take more Lipantil Supra than you should

If you take more Lipantil Supra than you should or if someone else has taken your medicine, tell your doctor or contact your nearest hospital.

If you forget to take Lipantil Supra

- If you forget a dose, take the next dose at the usual time.
- Then take your next tablet at the normal time.
- Do not take a double dose to make up for a forgotten dose.

If you are worried about this talk to your doctor.

If you stop taking Lipantil Supra

Do not stop taking Lipantil Supra unless your doctor tells you to, or the tablets make you feel unwell. This is because abnormal levels of fats in the blood need treating for a long period of time.

Remember that as well as taking Lipantil Supra it is also important that you:

- have a low fat diet
- take regular exercise.

If your doctor stops your medicine, do not keep any left-over tablets unless your doctor tells you to. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Lipantil Supra and see a doctor straight away, if you notice any of the following serious side effects – you may need urgent medical treatment:

- allergic reaction - the signs may include swelling of the face, lips, tongue or throat, which may cause difficulty in breathing
- cramps or painful, tender or weak muscles - these may be signs of muscle inflammation or breakdown, which can cause kidney damage or even death
- stomach pain - this may be a sign that your pancreas is inflamed (pancreatitis)
- chest pain and feeling breathless - these may be signs of a blood clot in the lung (pulmonary embolism)
- pain, redness or swelling in the legs - these may be signs of a blood clot in the leg (deep vein thrombosis)
- yellowing of the skin and whites of the eyes (jaundice), or an increase in liver enzymes – these may be signs of an inflamed liver (hepatitis).

Stop taking Lipantil Supra and see a doctor straight away, if you notice any of the side effects above.

Other side effects include:**Common** (affects less than 1 in 10 people):

- diarrhoea
- stomach pain
- wind (flatulence)
- feeling sick (nausea)
- being sick (vomiting)
- raised levels of liver enzymes in the blood – shown in tests.

Uncommon (affects less than 1 in 100 people):

- headache
- gallstones
- reduced sex drive
- rash, itching or red patches on the skin
- increase in creatinine (produced by the kidneys) – shown in tests.
- pancreatitis (inflammation of the pancreas leading to abdominal pain)
- thromboembolism: pulmonary embolism (blood clot in the lung causing chest pain and breathlessness), deep vein thrombosis (blood clot in the leg causing pain, redness or swelling)
- muscle pain, muscle inflammation, muscle cramps and weakness

Rare (affects less than 1 in 1,000 people):

- hair loss
- feeling dizzy (vertigo)
- feeling exhausted (fatigue)
- increase in urea (produced by the kidneys) – shown in tests
- increased sensitivity of your skin to sunlight, sun lamps and sunbeds
- drop in haemoglobin (that carries oxygen in blood) and white blood cells – shown in tests.
- hepatitis (inflammation of the liver), symptoms of which may be mild jaundice (yellowing of the skin and whites of the eyes), stomach pain and itching
- hypersensitivity (allergic reaction)

Side effect where the chance of it happening are not known

- severe form of skin rash with reddening peeling and swelling of the skin that resembles severe burns
- long-term lung problems
- muscle breakdown
- complications of gallbladder stones
- If you get any unusual breathing discomfort, tell your doctor straight away.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.hpra.ie E-mail: medsafety@hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Lipantil Supra

Do not store above 30°C.

Keep this medicine out of the sight and reach of children.

Do not take Lipantil Supra after the expiry date which is stated on the carton and on the blister. The expiry date refers to the last day of the stated month.

Take any tablets that are out of date, or which you no longer need, back to your pharmacist.

If your medicine appears to be discoloured, damaged, or shows any other signs of deterioration, please return it to your pharmacist who will advise you further.

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 to protect the environment.

6. Contents of the pack and other information**What Lipantil Supra contains**

Each film-coated tablet contains 145mg of fenofibrate. This is the active ingredient.

Each tablet also contains the following inactive ingredients:

Tablet core: sucrose, lactose monohydrate, microcrystalline cellulose and colloidal anhydrous silica, crospovidone, hypromellose, sodium lauril sulfate, docusate sodium, magnesium stearate.

Tablet coating: polyvinyl alcohol, titanium dioxide (E171), talc, soya lecithin and xanthan gum.

What Lipantil Supra looks like and contents of the pack

Lipantil Supra are white, oblong, film-coated tablets engraved "145" on one side and "Fournier logo" on the other side.

Lipantil Supra comes in blister packs of 30 tablets (3 blister strips of 10 tablets) or 90 tablets (9 blister strips of 10 tablets).

Manufacturer

Manufactured by: Mylan Laboratories SAS, Route de Belleville, Lieu-dit-Maillard, F 01400 Châtillon-sur-Charlaronne, France.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

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