

PACKAGE LEAFLET: INFORMATION FOR THE USER

Lipantil Supra® 145 mg film-coated tablet

fenofibrate

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. See section 4.

What is in this leaflet:

1. What Lipantil Supra is and what it is used for
2. What you need to know before you take Lipantil Supra
3. How to take Lipantil Supra
4. Possible side effects
5. How to store Lipantil Supra
6. 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 peanuts, arachis oil, soya lecithin or related products
- while taking other medicines, (such as other fibrates or an anti-inflammatory medicine called 'ketoprofen').
- you have had an allergic reaction or skin damage from sunlight or UV light you 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 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 (hypo-thyroidism)

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 and effects on muscles

Stop taking Lipantil Supra and see a doctor straight away if you get

- unexplained cramps
- painful, tender or weak muscles

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 treatment begins.

The risk of muscle problems is higher in some patients. In particular, 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 a 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 or pharmacist 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). This is because taking a statin or another fibrate in addition to 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.

Pregnancy and breast-feeding

- Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby. This is because it is not known how Lipantil Supra may affect your unborn baby. You should only use Lipantil Supra if your doctor tells you to.

Do not use Lipantil Supra if you are breast-feeding or planning to breast-feed your baby. This is because it is not known whether Lipantil Supra passes into human breast-milk. Therefore, you should not use Lipantil Supra if you are breast-feeding or planning to breast-feed your baby.

Driving and using machines

This medicine will not affect your ability to drive or use tools or machines.

Lipantil Supra contains sugars called lactose and sucrose.

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 peanuts, arachis oil or soya, do not take this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially sodium-free.

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.

Your doctor will determine the appropriate strength for you, depending on your condition, your current treatment and your personal risk status.

Taking this medicine

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

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

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

- have a low fat diet
- take regular exercise.

How much to take

The recommended dose is one tablet a day.

If you are already taking one 200mg capsule of Lipantil Micro 200 mg or one 160mg tablet of Lipantil Supra 160 mg a day, you can change to taking one 145mg tablet of Lipantil Supra 145 mg a day. You will still receive the same amount of medicine

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 adolescent

The use of Lipantil Supra is not recommended in children and young people 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 to take a dose, take the next dose at the usual time.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Lipantil Supra

Do not stop taking Lipantil Supra unless your doctor tells you to, or the tablet may make you feel unwell. This is because you require long-term

treatment. If your doctor stops your medicine, do not keep any leftover tablets unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor, or pharmacist.

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:

Uncommon: may affect up to 1 in 100 people

- 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)

Rare: may affect up to 1 in 1,000 people

- allergic reaction – the signs may include swelling of the face, lips, tongue or throat, which may cause difficulty in breathing
- 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).

Not known: it is not known how often these happen

- severe skin rash which reddens, peels and swells and looks like a severe burn
- long-term lung problems

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

Other side effects

Tell your doctor or pharmacist if you notice any of the following side effects:

Common may affect up to 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.
- increase in homocysteine (too much of this amino acid in the blood has been associated to a higher risk of coronary heart disease, stroke and peripheral vascular disease, although a causal link has not been established)

Uncommon may affect up to 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.

Rare may affect up to 1 in 1,000 people

- hair loss
- increase in urea (produced by the kidneys) – shown in tests
- skin is more sensitive to sunlight, sun lamps and sunbeds
- drop in haemoglobin (that carries oxygen in blood) and white blood cells – shown in tests

Not known: it is not known how often these happen

- muscle breakdown
- complications with gallbladder stones
- feeling exhausted

Tell your doctor or pharmacist if you notice any of the side effects listed above.

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 HPRAs Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lipantil Supra

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

Keep this medicine below 30 °C. Store in the original package in order to protect from light and moisture.

Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP/CAD. The expiry date refers to the last day of that month.

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

- The active substance is fenofibrate. Each Lipantil Supra 145 tablet contains 145 milligrams (mg) of fenofibrate.
- The other ingredients are: sucrose, lactose monohydrate, silicified microcrystalline cellulose, crospovidone, hypromellose, sodium laurilsulfate, docusate sodium, magnesium stearate.

The tablet coating Opadry® also contains: polyvinyl alcohol, titanium dioxide (E 171), talc, soybean lecithin, xanthan gum.

What Lipantil Supra looks like and contents of the pack

Lipantil Supra 145 film-coated tablets are white, oblong, engraved "145" on one side and "Fournier logo" on the other side. The film-coated tablets are provided in blister packs of 30.

Manufacturer

Recipharm Fontaine, Rue des Pres Potets, 21121 Fontaine-Les-Dijon, France or Mylan Laboratories SAS, Route de Belleville Lieu dit Maillard, F-01400 Chatillon-sur-Chalaronne, France.

Product procured from within the EU, repackaged and distributed by the parallel product authorisation holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Product Authorisation Number: PPA 465/409/1

Lipantil Supra is a registered trademark of BGP Products Operations GmbH

This medicinal product is authorised in the Member States of the EEA under the following names:

For MRP No. DE/H/0497/001:

- Germany: Lipidil 145 ONE
- Austria: Lipanthyl Nanopartikel 145 mg
- Belgium: Lipanthylnano 145 mg
- Luxembourg: Lipanthylnano 145 mg
- Czech Republic: Lipanthyl NT 145 mg
- Finland: Lipanthyl Penta 145 mg
- France: Lipanthyl 145 mg
- Greece: Lipidil NT 145 mg
- Hungary: Lipanthyl NT 145 mg
- Ireland: Lipantil supra 145 mg
- Italy: Fulcrosupra 145 mg
- Poland: Lipanthyl NT 145
- Slovak Republic: Lipanthyl NT 145 mg
- Spain: Secalip 145 mg

For MRP No. DE/H/0498/001:

- Germany: Xafenor 145 mg
- Italy: Fenolib 145 mg
- Portugal: Supralip 145 mg

For MRP No. DE/H/0500/001:

- Germany: Liperial 145 mg
- France: Fenofibrate Fournier 145 mg
- Italy: Liperial 145 mg

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