PACKAGE LEAFLET: INFORMATION FOR THE USER

Lipantil® Supra 215 mg film-coated tablets

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 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, or pharmacist or nurse. 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

Lipantil® Supra 215 mg contains the active substance fenofibrate and 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.

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: Further 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')
- 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 or nurse before taking this medicine 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) and an increase in liver enzymes (shown in blood tests)
- 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.

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 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). 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 - used to suppress your immune system

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

Lipantil® Suprawith food, drink and alcohol

It is important to take the tablet with food - it will not work as well if your stomach is empty.

Pregnancy, breast-feeding and fertility

- Do not take Lipantil® Supra and tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.
- Do not take Lipantil® Supra if you are breast-feeding or planning to breast-feed 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 (a type 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 Sunset yellow lake (E110) and Allura red AC lake (E129). These excipients may cause allergic reactions.

Lipantil® Supra contains soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, 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

- Swallow the tablet whole with a glass of water.
- Do not crush or chew the tablet.
- Take the tablet with food - it will not work as well if your stomach is empty.

How much to take

The recommended dose is one tablet of Lipantil® Supra (160 mg) a day.
However your doctor may want you to take one tablet of Lipantil® Supra (215 mg) a day. This is a higher dose.
If you are currently taking one capsule of Lipantil® Supra (267 mg), your doctor may change to one tablet of Lipantil® Supra (215 mg).

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 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 with your next meal.
- 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 you have any further questions on the use of this medicine, ask your doctor or 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.

- 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 (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.

Rare (affects less than 1 in 1,000 people):
- hair loss
- 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 the blood) and white blood cells - shown in tests.

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. If you get any unusual breathing discomfort, tell your doctor straight away.
- feeling exhausted (fatigue)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA 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 in the original package in order to protect from moisture.

This medicine does not require any special temperature storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP. 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. Content of the pack and other information

What Lipantil® Supra contains

- The active substance is fenofibrate. Each Lipantil® Supra 215 tablet contains 215 miligrams (mg) of fenofibrate.
- The other ingredients are: lactose monohydrate, sodium laurilsulfate, povidone, crospovidone, microcrystalline cellulose, silica colloidal anhydrous, sodium stearyl fumarate.The tablet coating Opadry®is made of polyvinyl alcohol, titanium dioxide (E 171), talc, soybean lecithin, xanthan gum, sunset yellow lake (E110), allura red AC lake (E129), indigo carmine lake (E132).

What Lipantil® Supra looks like and contents of the pack

Lipantil® Supra 215 mg film-coated tablets are orange-red in colour and oblong, engraved with 215 on one face.
The tablets are provided in blister packs of 28/30/56/100.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Marketing Authorisation Holder:
Mylan IRE Healthcare Limited,
Unit 35/36,
Grange Parade,
Baldoyle Industrial Estate,
Dublin 13,
Ireland

Manufacturer:

Astrea Fontaine

Rue des Prés Potets

21121 Fontaine les Dijon

France

Delpharm L'Aigle

Zone Industrielle No. 1

Route Crulai

61300 L'Aigle

France

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

Ireland:	Lipantil Supra 215 mg
Czech Republic:	Lipanthyl S 215 mg
Slovak Republic:	Lipanthyl Supra 215 mg
Poland:	Lipanthyl Supra 215 mg

This leaflet was last revised in June 2022