

Lipantil® Micro 200mg capsules, hard

Fenofibrate

PILLIPM200/2

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 Lipantil Micro is and what it is used for
2. What you need to know before you take Lipantil Micro
3. How to take Lipantil Micro
4. Possible side effects
5. How to store Lipantil Micro
6. Contents of the pack and other information

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

Lipantil Micro 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 Micro 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 Micro can be used in addition to other medicines (called '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 Micro**Do not take Lipantil Micro 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)
- 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 Micro if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Lipantil Micro.

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), 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 Micro.

Lipantil Micro and effects on muscles

Stop taking Lipantil Micro 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 starting treatment.

The risk of muscle breakdown 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 drink large amounts of alcohol
- you or a close family member has a muscle problem which runs in the family
- 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 Micro.

Other medicines and Lipantil Micro

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 Micro may increase the risk of muscle problems
- a particular class of medicines to treat diabetes (such as rosiglitazone or pioglitazone)
- cyclosporine (an immunosuppressant)

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

Pregnancy, breast-feeding and fertility

- Tell your doctor if you are pregnant, think you might be pregnant or are planning to have a baby. This is because it is not known how Lipantil Micro may affect your unborn baby. You should only use Lipantil Micro if your doctor tells you to.
- Do not use Lipantil Micro if you are breast-feeding or planning to breast-feed your baby. This is because it is not known whether Lipantil Micro passes into human breast milk.

Driving and using machines

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

Lipantil Micro contains sugars called lactose

- Lipantil Micro contains sugars called lactose. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance), talk to your doctor before taking this medicine.

3. How to take Lipantil Micro

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

Take the capsule with food – it will not work as well if your stomach is empty.

- Swallow the capsule whole with a glass of water.
- Do not open or chew the capsule.

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

- have a low fat diet
- take regular exercise.

How much to take

The usual dose is one capsule (200 mg) a day.

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 Micro is not recommended in children and young people under 18 years.

If you take more Lipantil Micro than you should

If you take more Lipantil Micro 200 mg 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 Micro

- If you forget a dose, take the next dose with your next meal.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Lipantil Micro

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

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, Lipantil Micro can cause side effects, although not everybody gets them.

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

Other side effects include:

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 (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 (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 (fatigue)

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 or pharmacist. 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 Micro

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

Store in the original package in order to protect from moisture. Do not store above 30°C.

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 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 Micro contains

- The active substance is fenofibrate. Each Lipantil Micro 200 capsule contains 200 milligrams (mg) of fenofibrate.
- The other ingredients are: lactose monohydrate, sodium laurilsulfate, pregelatinised maize starch, crospovidone and magnesium stearate. The capsule is made of gelatin, titanium dioxide (E171), red iron oxide (E172), yellow iron oxide (E172).

What Lipantil Micro looks like and contents of the pack

Lipantil Micro 200 mg capsules are ochre and hard. The capsules are provided in blister packs of 30.

Manufacturer and Parallel Product Authorisation Holder

Manufacturer:

Recipharm Fontaine
Rue des Prés Potets
21121 Fontaine les Dijon
FRANCE

or

Famar L'Aigle
Zone Industrielle No. 1
Route Crulai
61300 L'Aigle
France

Parallel Product Authorisation Holder:

Procured from within the EU by the Parallel Product Authorisation Holder: Primecrown 2010 Ltd., 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS, UK.

Repackager:

Repackaged by Primecrown Ltd., 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS, UK or Propack Health Ltd., 3-4 Ballyboggan Industrial Estate, Ballyboggan Road, Finglas, Dublin 11.

Distributed by Merit Pharmaceuticals, Swords, County Dublin.

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

Ireland: LIPANTIL Micro 200 mg hard capsules

Sweden: LIPANTHYL 200 mg capsules

PILLIPM200/2

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