LIPANTHYL® PENTA 145MG FILM COATED TABLET

Fenofibrate 145mg

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What LIPANTHYL® is used for LIPANTHYL® 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

LIPANTHYL® 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

How LIPANTHYL® works

LIPANTHYL® 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

Before you use LIPANTHYL®

When you must not use it

Do not take LIPANTHYL® if:

- you are allergic to fenofibrate or any of the other ingredients of this medicine (listed in Section 8: Product Description)
- you are allergic (hypersensitive) 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 (those 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 LIPANTHYL® if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking LIPANTHYL®

Before you start to use it

Talk to your doctor or pharmacist or nurse before taking LIPANTHYL® 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 LIPANTHYL®.

Taking other medicines

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 LIPANTHYL® increase the risk of muscle problems
- a particular class of medicines to treat diabetes (such as rosiglitazone or pioglitazone)
- ciclosporin (an immunosuppressant)

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

How to use LIPANTHYL®

How much to use

In adults and elderly patients:

The recommended dosage is one tablet a day

In patients with renal impairment (kidney problems):
A reduced dose is recommended. A lower dose of fenofibrate should be used.

In patient with hepatic impairment (liver problems) :
LIPANTHYL® is not recommended since not enough data are available

In younger patients and infants:
LIPANTHYL® is not recommended in children and adolescent less than 18 years old since not enough data are

When to use it

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

- Swallow the tablet with a glass of water.
- Do not crush or chew the tablet.
- the tablet can be eaten at any time with or without food

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How long to use it

Do not stop taking LIPANTHYL® 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 LIPANTHYL® 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 or

If you forget to take it

- If you forget a dose, take as soon as you remember, if it is still early
- 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 take too much (overdose)

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

While you are using LIPANTHYL®

Things you must do

Stop taking LIPANTHYL® 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 problems 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

Things you must not do

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 the use of LIPANTHYL® during pregnancy, you should use LIPANTHYL® only, if your doctor considers it absolutely

It is not known, whether the active substance in LIPANTHYL® passes into breast-milk.
Therefore, you should not use LIPANTHYL® if you are breast-feeding or planning to breast-feed

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.

Things to be careful of

LIPANTHYL® contains lactose and sucrose (types of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars (have intolerance to some sugars), talk to your doctor before taking this

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

Side effects

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

Stop taking LIPANTHYL® 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)

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- 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 LIPANTHYL® 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
- skin rash, itchy skin
- sexual dysfunction
- 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 that have been reported by patients, but 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website www.npra.gov.my (Consumers - Reporting)

Storage and Disposal of LIPANTHYL®

Storage

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

Disposal

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.

Product Description

What it looks like

White oblong white film-coated tablet engraved "145" on one side and "Fournier Logo" on the other side.
Box of 30 tablets

Ingredients

The active substance is Fenofibrate 145mg.
The other ingredients are;
Core: sucrose, lactose monohydrate, silicified microcrystalline cellulose, crospovidone, hypromellose, sodium lauryl sulfate, docusate sodium, magnesium stearate.

Coating: polyvinyl alcohol, titanium dioxide (E171), talc, soybean lecithin, xanthan gum

MAL Number

MAL10053648ARZ

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Manufacturer and Product Registration Holder

Manufacturer
Abbott Healthcare Private Limited
Village Bhatauli Khurd, Sai Road,
District Solan, Baddi, 173205, India

Packer and Batch Releaser
Astrea Fontaine
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Product Registration Holder
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