

## PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S3**

### LIPANTHYL 145 mg film-coated tablets

Fenofibrate.

Each film-coated tablet contains sugar (132,00 mg lactose monohydrate and 145,00 mg sucrose).

#### Read all of this leaflet carefully before you start taking LIPANTHYL 145 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- LIPANTHYL 145 mg has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

#### What is in this leaflet

1. What LIPANTHYL 145 mg is and what it is used for.
2. What you need to know before you take LIPANTHYL 145 mg.
3. How to take LIPANTHYL 145 mg.
4. Possible side effects.
5. How to store LIPANTHYL 145 mg.
6. Contents of the pack and other information.

#### 1. What LIPANTHYL 145 mg is and what it is used for

LIPANTHYL 145 mg belongs to a group of medicines called fibrates that are used to lower lipid (fat) levels (for example the fats known as triglycerides).

LIPANTHYL 145 mg is used in association with a low-fat diet and other non-medical treatments, such as exercise and weight loss, to reduce the levels of fat in your blood.

In some cases, LIPANTHYL 145 mg can be used in addition to other medicines (called statins) if blood lipid concentrations cannot be controlled with a statin alone.

LIPANTHYL 145 mg can also be used in patients with type 2 Diabetes to reduce the progression of diabetic retinopathy (an eye condition that can cause vision loss and blindness).

## **2. What you need to know before you take LIPANTHYL 145 mg**

### **Do not take LIPANTHYL 145 mg:**

- If you are hypersensitive (allergic) to fenofibrate or any of the other ingredients of LIPANTHYL 145 mg (see section 6);
- if you have severe liver, kidney or gallbladder problems;
- if you have pancreatitis (inflammation of the pancreas which causes abdominal pain) which is not caused by high levels of fat in your blood;
- if you have had an allergic reaction or skin damage on exposure to sunlight or UV light while you were taking other medicines (including other fibrates or anti-inflammatory medicines such as ketoprofen);
- if you are allergic to peanuts, groundnut oil (arachis oil), soya lecithin or related products.

Do not take LIPANTHYL 145 mg if one of the afore-mentioned points applies to you. If you are unsure, talk to your doctor or pharmacist before taking LIPANTHYL 145 mg.

### **Warnings and precautions**

Take special care with LIPANTHYL 145 mg:

- If you have any liver or kidney problems;
- if you experience any liver problems while taking LIPANTHYL 145 mg, you may be suffering from hepatitis (inflammation of the liver). Typical signs of hepatitis include yellow discolouration of the skin and whites of the eyes (jaundice), an increase in liver enzymes (confirmed by blood tests), abdominal pain and itching;

- you have diabetes (high blood sugar), especially Type 2 diabetes, that is not well controlled;
  - if you have an underactive thyroid (hypothyroidism);
  - if you have problems with certain proteins in your blood;
  - if you have an alcohol problem (high alcohol intake);
  - if you are taking other medicines (including diuretics, beta-blocking agents, oestrogens, progestogens, combined oral contraceptives, immunosuppressants and protease inhibitors);
- Some of the above conditions can lead to high levels of lipids in your blood and need to be corrected before you start treatment with LIPANTHYL 145 mg.

#### **LIPANTHYL 145 mg and effects on muscles**

LIPANTHYL 145 mg can cause serious muscle problems. These problems rarely occur but can lead to inflammation and muscle decay, and potentially kidney damage or even death. Stop taking LIPANTHYL 145 mg and contact your doctor immediately if you notice the following symptoms:

- unexplained cramps;
- painful, sensitive or weak muscles.

Your doctor may perform a blood test, before and after treatment, to check your muscles.

Some patients are more prone to muscle problems. Inform your doctor in particular if you:

- are over 70 years of age;
- or if a close family member has muscle problems and there is a family history of muscle problems;
- have kidney problems;
- have thyroid problems (hypothyroidism);
- drink large quantities of alcohol;
- take medicines called statins (used to lower your lipid levels in your blood);
- experienced muscle problems whilst taking statins or fibrates (medicines used lower lipid levels in your blood).

If one of the afore-mentioned points applies to you (or if you are not entirely sure), talk to your doctor before taking LIPANTHYL 145 mg.

### **Other medicines and LIPANTHYL 145 mg**

Always tell your health care provider if you are taking any other medicine. This includes complementary or traditional medicines.

Tell your doctor or pharmacist if you are currently using:

- anti-coagulant medicines (used to thin your blood and prevent blood clot formation);
- cyclosporine (used to suppress your immune system);
- other medicines used to control your lipid levels (such as statins or fibrates) as the additional intake of another statin or fibrate in conjunction with LIPANTHYL 145 mg could increase the risk of muscle problems;
- glitazones, a specific group of medicines to treat diabetes.

### **LIPANTHYL 145 mg with food, drink and alcohol**

See section 3.

### **Pregnancy, breastfeeding and fertility**

You should not take LIPANTHYL 145 mg if you are pregnant.

You should not take LIPANTHYL 145 mg if you are breastfeeding or intend to breastfeed. It is not known whether LIPANTHYL 145 mg passes into breast milk.

### **Driving and using machines**

LIPANTHYL 145 mg is unlikely to have an effect on your ability to drive a vehicle and use machines.

**LIPANTHYL 145 mg contains lactose and sucrose**

LIPANTHYL 145 mg contains sugar (lactose and sucrose). If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking LIPANTHYL 145 mg.

LIPANTHYL 145 mg contains soya oil. If you are allergic to peanut or soya, do not use LIPANTHYL 145 mg.

**LIPANTHYL 145 mg contains sodium**

LIPANTHYL 145 mg contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

**3. How to take LIPANTHYL 145 mg**

Do not share medicines with any other person.

Always take LIPANTHYL 145 mg exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure. Your doctor will prescribe the appropriate dose depending on your state of health, current treatment and personal risk status.

Always take LIPANTHYL 145 mg exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Method of administration**

It can be taken at any time of the day regardless of a meal.

The film-coated tablet should be swallowed with a glass of water.

The film-coated tablet should not be crushed or chewed.

Remember that, in addition to taking LIPANTHYL 145 mg, it is also important to follow a low-fat diet exercise regularly.

**Dosage**

The usual dose is one film-coated tablet per day.

If you are already taking one capsule containing 200 mg fenofibrate per day or 160 mg fenofibrate per day, you can switch to one LIPANTHYL 145 mg film-coated tablet per day. The quantity of active substance will be the same.

Do not exceed the recommended dosage.

If you have the impression that the effect of LIPANTHYL 145 mg is too strong or too weak, tell your doctor or pharmacist.

**Patients with kidney problems**

If you suffer from kidney problems, your doctor may prescribe a lower dose for you. Ask your doctor or pharmacist about it.

**Use in children and adolescents**

The safety and efficacy of LIPANTHYL 145 mg have not been sufficiently established in children and adolescents younger than 18 years.

LIPANTHYL 145 mg is not recommended for children and adolescents under 18 years of age.

**If you take more LIPANTHYL 145 mg than you should**

In the event of an overdose, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

Take this leaflet and the rest of the remaining LIPANTHYL 145 mg with you so the doctor will know what you have taken.

**If you forget to take LIPANTHYL 145 mg**

If you have forgotten a dose, take the next dose at the scheduled time.

Do not take a double dose to make up for forgotten individual doses.

#### **If you stop taking LIPANTHYL 145 mg**

Only stop taking LIPANTHYL 145 mg if your doctor tells you to do so or if the film-coated tablets make you feel unwell, because you require long-term treatment. If your doctor advises you to stop taking LIPANTHYL 145 mg, do not keep any unused tablets unless your doctor tells you to do so. If you have any further questions on the use of LIPANTHYL 145 mg, ask your doctor or pharmacist.

#### **4. Possible side effects**

LIPANTHYL 145 mg can have side effects.

Not all side effects reported for LIPANTHYL 145 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LIPANTHYL 145 mg, please consult your health care provider for advice.

If any of the following happens, stop taking LIPANTHYL 145 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to LIPANTHYL 145 mg. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

*Side effects occurring less frequently:*

- chest pain and shortness of breath (dyspnoea) - possible signs of a blood clot in the lungs (pulmonary embolism);
- pain, inflammation or swelling of the legs - possible signs of a blood clot in the leg (deep vein thrombosis);
- abdominal pain - which could be a sign of inflammation of the pancreas (pancreatitis);

- yellow discolouration of the skin and whites of the eyes (jaundice) or an increase in liver enzymes - possible signs of an inflamed liver (hepatitis).

*The following side effects may occur, but the frequency is not known:*

- severe rash in the form of redness, peeling and swelling of the skin, similar to severe burns - these may be signs of severe skin reactions (e.g. erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis);
- lung problems over a prolonged period;
- cramps or painful, sensitive or weak muscles - possible signs of muscle inflammation or breakdown, which may lead to kidney damage and even death.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

*Side effects occurring frequently:*

- Pain of your stomach area, nausea (feeling sick), vomiting (being sick), diarrhoea, excessive wind;
- increase in homocysteine levels (excess levels of this amino acid in the blood are associated with an increased risk of coronary heart disease, stroke and peripheral vascular disease - the precise causal relationship is not known).

*Side effects occurring less frequently:*

- headache;
- gallstones;
- hives;
- hair loss;
- sensitive skin on exposure to sunlight, sun lamps or sun beds;
- decrease in haemoglobin (which carries oxygen in the blood) and white blood cells - confirmed by blood tests;

- changes in your sex drive;
- increase in urea levels (produced by the kidneys) – confirmed by blood tests;
- increase in creatinine levels (produced by the kidneys) – confirmed by blood tests.

*The following side effects may occur, but the frequency is not known:*

- tiredness (lack of energy).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### **Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications: <http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of LIPANTHYL 145 mg. [pv.south-africa@abbott.com](mailto:pv.south-africa@abbott.com)

### **5. How to store LIPANTHYL 145 mg**

- Store at or below 30 °C. store in original container.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

### **6. Contents of the pack and other information**

#### **What LIPANTHYL 145 mg contains**

Each film-coated tablet contains 145 mg fenofibrate as nanoparticles.

The other ingredients are:

*Tablet core:*

Crospovidone  
Docusate sodium  
Hypromellose  
Lactose monohydrate  
Magnesium stearate  
Silicified microcrystalline cellulose  
Sucrose  
Sodium laurilsulphate  
Opadry OY-B-28920

*Film-coating:*

Opadry OY-B-28920 contains:

Polyvinyl alcohol  
Soybean lecithin  
Talc  
Titanium dioxide (E171)  
Xanthan gum

**What LIPANTHYL 145 mg looks like and contents of the pack**

White, oblong, film-coated tablets engraved "145" on one side and the "F" logo on the other.

Thermoformed blister strips (clear PVC/PE/PVDC sealed with aluminium complex) of 10 filmcoated tablets each.

Original pack size of:

- 30 film-coated tablets
- 100 film-coated tablets

Not all pack sizes may be marketed.

**Holder of certificate of registration**

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**This leaflet was last revised in**

12 March 2024

**Registration number**

56/7.5/0113