Abbott Laboratories South Africa (Pty) Ltd	LIPANTHYL 200 mg
Hard capsules	Reg No.: 30/7.5/0494

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

LIPANTHYL 200 mg hard capsules

Fenofibrate (micronised)

Contains sugar (101 mg lactose monohydrate per capsule)

Read all of this leaflet carefully before you start taking LIPANTHYL 200 mg.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- LIPANTHYL 200 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 200 mg is and what it is used for
2. What you need to know before you take LIPANTHYL 200 mg
3. How to take LIPANTHYL 200 mg
4. Possible side effects
5. How to store LIPANTHYL 200 mg
6. Content of the pack and other information

1. What LIPANTHYL 200 mg is and what it is used for

LIPANTHYL 200 mg belongs to a group of medicines, known as 'fibrates'. These medicines are used to lower the level of fats (lipids or triglycerides) in the blood. LIPANTHYL 200 mg is used, in combination with a low fat diet and other non-medical treatments such as exercise and weight loss, to lower levels of fats in the blood. LIPANTHYL 200 mg 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. LIPANTHYL 200 mg can often also increase the amount of a 'good' type of cholesterol, called HDL or high-density lipoprotein cholesterol. It is always essential to continue a low-fat diet during treatment with LIPANTHYL 200 mg.

2. What you need to know before you take LIPANTHYL 200 mg

Do not take LIPANTHYL 200 mg:

- if you are hypersensitive (allergic) to fenofibrate or any of the other ingredients of LIPANTHYL 200 mg (listed in section 6)
- if you are pregnant or are breastfeeding your baby
- if you have kidney stones (formation of stones along the urinary tract, causing pain when passing through)
- if your liver or kidneys are not functioning well.

Warnings and precautions

Take special care with LIPANTHYL 200 mg:

- if you have high blood sugar (diabetes), especially type 2 diabetes, that is not well controlled
- if you have an under-active thyroid gland (hypothyroidism)
- if you have a kidney disorder that causes your body to pass too much protein in your urine (nephrotic syndrome)
- if you have problems with certain proteins in your blood (dysproteinaemia)

- if you have a condition where there is blockage of the flow of bile out of the liver (obstructive liver disease)
- if you have an alcohol problem
- if you are taking other medicines (see **Other medicines and LIPANTHYL 200 mg** below)
- if you have any liver or kidney problems
- if 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)
- if you have pancreatitis (inflamed pancreas causing sudden or severe stomach pain)
- if you have an underactive thyroid gland (hypothyroidism)
- if you or your family have had muscle problems
- if you are over 70 years of age (some of the above conditions can lead to high levels of lipids in your blood and need to be corrected before you start therapy with LIPANTHYL 200 mg).

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or health care provider before taking LIPANTHYL 200 mg. Your doctor might want to test your blood or urine to see if LIPANTHYL 200 mg is working properly and also if your kidneys, muscles and liver are working properly.

Your doctor might want to test your blood or urine to check if your LIPANTHYL 200 mg is working properly and also if your kidneys, muscles and liver are working properly.

Other medicines and LIPANTHYL 200 mg

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

The following medicines may cause an interaction when used together with LIPANTHYL 200 mg:

- anticoagulants, such as warfarin (used to thin your blood)
- statins or fibrates (used to control fat levels in your blood), may increase the risk of muscle problems
- ciclosporin (used to suppress your immune system)
- glitazones or other hypoglycaemic medicine (used to treat diabetes (high blood sugar)).

LIPANTHYL 200 mg with food, drink and alcohol

It is important to take LIPANTHYL 200 mg hard capsules 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.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking LIPANTHYL 200 mg.

Do not take LIPANTHYL 200 mg if you are pregnant or breastfeeding your baby.

Driving and using machines

LIPANTHYL 200 mg will not affect your ability to drive a vehicle or performing tasks requiring your attention.

LIPANTHYL 200 mg contains lactose

LIPANTHYL 200 mg 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 LIPANTHYL 200 mg.

3. How to take LIPANTHYL 200 mg

Do not share medicines prescribed for you with any other person.

Always take LIPANTHYL 200 mg exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual adult dose is one LIPANTHYL 200 mg capsule per day, every day, at about the same time each day.

If you take more LIPANTHYL 200 mg than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Always take the labelled medicine package with you, whether there are any LIPANTHYL 200 mg capsules left or not.

If you forget to take LIPANTHYL 200 mg

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

LIPANTHYL 200 mg can have side effects.

Not all side effects reported for LIPANTHYL 200 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LIPANTHYL 200 mg, please consult your health care provider for advice.

If any of the following happens, stop taking LIPANTHYL 200 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash, itching, urticaria (hives)
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to LIPANTHYL 200 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:

- cramps or painful, tender or weak muscles (these may be signs of muscle inflammation or breakdown, which can cause kidney damage)
- stomach pain (this may be a sign that your pancreas are 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)).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache
- feeling dizzy (vertigo)
- stomach pain, diarrhoea, 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).

Less frequent side effects:

- gallstones
- reduced sex drive
- increase in creatinine, which is produced by the kidneys (shown in tests)

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https//wwwsahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of LIPANTHYL 200 mg.

5. How to store LIPANTHYL 200 mg

Store at or below 25 °C in a dry place and protect from light.

Store all medicines out of reach for 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

The active substance is fenofibrate (micronised).

Each LIPANTHYL 200 mg capsule contains 200 milligrams (mg) of fenofibrate.

The other ingredients are lactose monohydrate, pregelatinised starch, sodium laurilsulfate crospovidone, magnesium stearate.

The capsule is made of gelatine, titanium dioxide (E171), red iron oxide (E172) and yellow iron oxide (E172).

What LIPANTHYL 200 mg looks like and contents of the pack

Number 1 hard gelatine capsule with orange cap and body, containing a whitish powder.

Blister packs of 2 x 15 capsules.

Holder of Certificate of Registration

Abbott Laboratories S.A. (Pty) Ltd

Abbott Place

219 Golf Club Terrace

Constantia Kloof 1709

South Africa

011 858 2000

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