PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

PROPRIETARY NAME AND DOSAGE FORM:

LOPID® 600 tablet

Gemfibrozil

Read all of this leaflet carefully before you start taking LOPID.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- LOPID 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 LOPID CONTAINS:

Each LOPID tablet contains 600 mg of the active ingredient gemfibrozil.

LOPID tablets contain the following inactive ingredients: microcrystalline cellulose, pregelatinised starch, colloidal anhydrous silica, polysorbate 80, sodium starch glycollate, magnesium stearate, methyl hydroxypropyl cellulose, titanium dioxide, talc, polydimethyl siloxane and polyethylene glycol 6000.
Sugar free.

WHAT LOPID IS USED FOR:

LOPID belongs to a group of medicines called “lipid regulating medicines”. It is used to lower fats (lipids) known as bad cholesterol (LDL cholesterol) and triglycerides in your blood and increase good cholesterol (HDL cholesterol).

LOPID must be used alongside a low fat diet and other non-medical treatments such as exercise and weight loss.

BEFORE YOU TAKE LOPID:

Do not take LOPID:

- If you are hypersensitive (allergic) to gemfibrozil or any of the ingredients contained in LOPID tablets.
- If you have any form of liver disease.
- If you have any form of kidney disease.
- If you suffer from gallstones or any other disease of the biliary tract.
- If you are taking simvastatin (a medicine used to lower your cholesterol).
- If you are diabetic and are taking repaglinide (a medicine used to reduce your blood sugar).
- If you are taking dasabuvir (a medicine used to treat hepatitis C).
- If you are taking selexipag (a medicine used to treat high blood pressure).

Take special care with LOPID:

Make sure your doctor knows:

- If you drink large amounts of alcohol.
- If you experience muscle weakness, tenderness or pain be sure to tell your doctor who will give you advice on how to avoid these symptoms occurring.
- If you are thinking of becoming pregnant.

During treatment with LOPID, your doctor will periodically monitor your:

- liver function tests
- blood cell counts
- blood sugar levels.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking this medicine.

Do not take LOPID if you are pregnant or are breastfeeding.

Driving and using machinery:

In rare cases, LOPID may make you feel dizzy and affect your eyesight. If you are affected, do not drive or operate machinery.

Taking other medicines with LOPID:

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

There are some medicines that may change the effect of LOPID, or their effect may be changed by LOPID. This type of interaction could make one or both of the medicines less effective.

Make sure your doctor knows if you are taking any of the following medicines:

- Warfarin (used to thin your blood).
- Statins such as atorvastatin, simvastatin, lovastatin, pravastatin and rosuvastatin (used to lower your bad cholesterol and triglycerides and increase your good cholesterol).
- Medicines used to treat various types of cancer (e.g. dabrafenib, enzalutamide and paclitaxel).
- Loperamide (used to treat diarrhoea).
- Montelukast (used in the treatment of allergic rhinitis, hay fever and asthma).
- Any anti-diabetic medicines, particularly repaglinide, pioglitazone or rosiglitazone (used to help reduce your blood sugar).
- Colchicine (used to treat gout).

If you are taking any resin granules for your hyperlipidaemia (too much bad fat in your blood) e.g. colestipol, **do not** take them at the same time as LOPID or for at least two hours before, or for at least two hours after taking LOPID. If you do, you will make LOPID less effective.

HOW TO TAKE LOPID:

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

Always take LOPID exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Before you take LOPID, your doctor will try to control your blood lipids by treating any underlying conditions (such as thyroid disease or diabetes) and will give you advice about eating the correct diet, exercising, giving up smoking, cutting down on alcohol and, if necessary, losing weight.

The dose range of LOPID is 900 mg to 1 200 mg daily. Your doctor will decide what dose is right for you.

If you are advised to take a 1 200 mg dose, you will need to take one tablet twice daily, half an hour before your breakfast and half an hour before your evening meal. Swallow your tablets whole, with a glass of water or milk.

Your doctor will tell you how long your treatment with LOPID will last. Do not stop treatment early. If you have the impression that the effect of LOPID is too strong or too weak, tell your doctor or pharmacist.

Use in children:

LOPID is not recommended for use in children.

If you take more LOPID than you should:

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

Symptoms reported with overdosage were abdominal cramps, abnormal LFTs, diarrhoea, increased CPK, joint and muscle pain, nausea and vomiting.

If you forget to take LOPID:

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

POSSIBLE SIDE EFFECTS:

LOPID tablets can have side effects.

Not all side effects reported for LOPID are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare provider for advice.

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

- If you experience angioedema and your face and tongue start to swell up, it may cause difficulty in breathing.
- If you experience muscle weakness, tenderness or pain, especially if accompanied by dark coloured urine, fever, rapid heart rate, nausea and vomiting.
- If you experience yellowing of the skin and eyes (also called jaundice).

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

Frequent side effects reported during controlled clinical trials include gastrointestinal reactions, indigestion, heartburn and flatulence, stomach pain, diarrhoea, nausea or vomiting and constipation. Acute appendicitis, irregular heartbeat, tiredness, rash (particularly itchy skin or puffy rash), dizziness, and headache have also been reported.

Other side effects reported may include blood disorders, decreased libido, depression, sleepiness, loss of feeling and tingling sensation, blurred vision, sore throat, inflammation of the pancreas, allergic skin reaction, itchy skin, painful joints, muscle disease (myopathy) muscle weakness, painful muscles, muscle breakdown (rhabdomyolysis), loss of sexual ability, photosensitivity (a sensitivity to light that can cause skin discolouration or a rash), hair loss, inflammation of the gall bladder and gall stones.

If any of these side effects continue, are severe or bother you, tell your doctor or pharmacist.

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

STORAGE AND DISPOSAL OF LOPID:

Store all medicines out of reach of children.

Store at or below 25 °C in a cool, dry place.

Do not use after the expiry date stated on the label.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF LOPID:

LOPID tablets are available in blister packs containing 60 tablets.

IDENTIFICATION OF LOPID:

LOPID tablets are white, film-coated, oval biconvex.

REGISTRATION NUMBER:

Y/7.5/245

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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