Package leaflet: Information for the user

LOPID 300 mg capsules, hard
LOPID 600 mg film-coated tablets

gemfibrozil

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 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. See section 4.

What is in this leaflet

1. What Lopid is and what it is used for

Lopid contains the active substance gemfibrozil which 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.

Lopid is used, alongside a low fat diet and other non-medical treatment such as exercise and weight loss, to lower levels of fat in the blood. Lopid can be used when other medicines (statins) are unsuitable, to reduce the occurrence of heart problems in men who are at high risk and who have increased 'bad cholesterol'.

Lopid may also be prescribed to people who cannot be prescribed other lipid-lowering medicines for lowering blood cholesterol levels.

2. What you need to know before you take Lopid

Do not take Lopid

- if you are allergic to gemfibrozil or any of the other ingredients of this medicine (listed in section 6)
- if you have liver disease
- if you have severe kidney disease
- if you have a history of gall stones, bile and gall bladder disease (biliary tract disease)
- if in the past you have had photoallergy or a phototoxicity reaction (allergic reaction triggered by exposure to sunlight) during treatment with fibrates
- if you are currently taking a medicine called repaglinide (a drug used to reduce blood sugar levels in diabetes), simvastatin, or rosuvastatin at 40 mg (cholesterol lowering medicines), or dasabuvir (a drug used to treat hepatitis C infection), or selexipag (a drug used to treat pulmonary arterial hypertension)

Warnings and precautions

Talk to your doctor or pharmacist before taking Lopid.
Tell your doctor if you have any of the following conditions to help decide if Lopid is suitable for you:
- high risk of muscle breakdown (rhabdomyolysis): risk factors include kidney impairment; under-active thyroid; over 70 years; excessive use of alcohol; previous history of muscular pain and weakness (muscular toxicity) with another fibrate or statin; a history of inherited muscular disorders; use of Lopid in combination with statins used to lower bad cholesterol and triglycerides, and increase good cholesterol such as rosuvastatin and simvastatin (for simvastatin and rosuvastatin 40 mg see "Do not take Lopid" and see "Other medicines and Lopid")
- mild or moderate kidney disease
- under-active thyroid
- diabetes

Other medicines and Lopid
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
- anti-diabetic medication particularly rosiglitazone or repaglinide (used to help reduce blood sugar levels) (for repaglinide see "Do not take Lopid")
- dasabuvir, a drug used to treat hepatitis C infection (see "Do not take Lopid" above)
- selexipag, a treatment for pulmonary hypertension (see "Do not take Lopid" above)
- statins used to lower bad cholesterol and triglycerides, and increase good cholesterol such as atorvastatin, lovastatin, pravastatin, rosuvastatin and simvastatin (for simvastatin and rosuvastatin at 40 mg see "Do not take Lopid" and see "Warnings and precautions")
- dabrafenib, a treatment for melanoma
- loperamide, a treatment for diarrhoea
- montelukast, a treatment for asthma
- pioglitazone, a treatment used for diabetes
- warfarin, acenocoumarol, and phenprocoumon (anticoagulants used to thin blood)
- colestipol resin granules for the treatment of high levels of fat (cholesterol) in your blood
- bexarotene medication for the treatment of skin cancer
- colchicine for the treatment of gout
- paclitaxel, a treatment for cancer
- enzalutamide, a treatment for prostate cancer

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Breast-feeding
It is recommended that you do not take Lopid while you breast-feed.

Driving and using machines

In rare cases Lopid may cause dizziness and affect your eyesight, if this happens, do not drive or operate machinery. You can drive or operate machinery as long as you feel well.

Dietary sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet and therefore is essentially 'sodium-free'.

3. How to take Lopid

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 blood lipid levels will be closely monitored and regularly assessed before and during your treatment with Lopid. If you are diabetic or have problems with your thyroid, your doctor will try to treat these conditions before you start treatment. Your doctor will also give you advice about eating the correct diet, exercising, giving up smoking, cutting down on alcohol and if necessary, losing weight.

Lopid should be taken orally. It is recommended that the capsules or tablets be swallowed with a glass of water as the tablets taste unpleasant if you break them.

Lopid with food and drink

Lopid should be taken half an hour before meals.

Adults and elderly:

The usual starting dose is between 900 mg and 1200 mg daily. Your doctor will decide the best dose for you, follow the instructions given on the label.

If you are advised to take a 1200 mg dose, you will need to take 600 mg half an hour before your breakfast and a second 600 mg half an hour before your evening meal.

If you are advised to take a 900 mg dose, you will need to take the dose half an hour before your evening meal.

Adults with mild or moderate kidney disease:

Your doctor will assess your condition before and during your treatment with Lopid. Your treatment will start at 900 mg daily and may be increased up to 1200 mg depending on your response. Lopid should not be used in patients with severe kidney disease.

Use in children

Lopid is not recommended for children.

If you take more Lopid than you should

If you accidentally take too much Lopid contact your doctor at once or go to the nearest hospital accident and emergency department. Always take the labelled medicine package with you, whether there is any Lopid left or not. Signs of overdose may be abdominal cramps, diarrhoea, joint and muscle pain, nausea and vomiting.

If you forget to take Lopid

If you forget to take a dose, do not worry. Simply miss that dose and take your next dose at the right time. **Do not take a double dose to make up for a forgotten dose.**

If you stop taking Lopid

Do not stop taking Lopid unless your doctor tells you to. **It is recommended that you follow all the advice given while you are taking Lopid so as to gain the full benefit of the treatment**.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Serious side effects

Although serious reactions can occur, you are advised to contact your doctor immediately if you get any of the following symptoms after taking Lopid:

Rare (may affect up to 1 in 1,000 people)

- allergic reaction in which the face, tongue or throat may start to swell up, causing difficulty in breathing (angioedema)
- peeling and blistering of the skin, mouth, eyes and genitals
- rash affecting your whole body
- muscle weakness or weakness accompanied by dark urine, fever, rapid heart rate (palpitations), nausea or vomiting

Other reported side effects include:

Very common side effects (may affect more than 1 in 10 people)

- indigestion

Common side effects (may affect up to 1 in 10 people)

- sense of spinning or swaying (vertigo)
- eczema, rash (particularly an itchy or puffy rash)
- headache
- stomach pain
- diarrhoea
- feeling sick
- being sick
- constipation
- wind
- tiredness

Uncommon side effects (may affect up to 1 in 100 people)

- irregular heartbeat

Rare (may affect up to 1 in 1,000 people)

- reduction or increase in white blood cells (leucopenia, eosinophilia), bone marrow disease (bone marrow failure)
- reduction of blood platelets (thrombocytopenia)
- inflammation of the nerves (peripheral neuropathy)
- unusual bruising or bleeding due to a reduction in blood platelets (thombocytopaenia)
- severe anaemia

- loss of feeling and a tingling sensation (paraesthesia)
- pancreatitis
- blurred vision
- jaundice (yellowing of the skin), disturbed liver function
- inflammation of the liver (hepatitis)
- gallstones (cholelithiasis), inflammation of the gall bladder (cholecystitis)
- appendicitis
- depression
- dizziness
- sleepiness
- painful joints and extremities
- inflammation of the skin or inflamed skin which flakes or falls off
- inflammation of the muscles (myositis)
- inflammation of the synovial membrane (synovitis)
- persistent lack of energy
- impotence
- decreased libido
- hair loss
- photosensitivity (a sensitivity to light that can cause skin discolouration or a rash)
- red, itchy raised areas of skin
- itching

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lopid

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

Do not use this medicine after the expiry date which is stated on the carton label and blister foil after EXP. The expiry date refers to the last day of that month.

Lopid 300 mg hard capsules: Store below 25ºC in the original package in order to protect from moisture.
Lopid 600 mg film-coated tablets: Store below 25ºC.

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 protect the environment.

6. Contents of the pack and other Information

What Lopid contains

Lopid 300 mg hard capsules
The active substance is gemfibrozil. Each hard capsule contains 300 mg gemfibrozil.
The other ingredients are polysorbate (E433), colloidal silica and maize starch.
The capsule shell contains gelatin, titanium dioxide (E171), erythrosine (E127) and indigo carmine (E132).
The printing ink contains shellac glaze and iron oxide black (E172).

Lopid 600 mg film-coated tablets
The active substance is gemfibrozil. Each film-coated tablet contains 600 mg gemfibrozil. The other ingredients are pregelatinised starch, microcrystalline cellulose, colloidal silica (anhydrous), sodium starch glycollate, polysorbate 80 (E433) and magnesium stearate.

The film coat for tablets contains hydoxypropylmethylcellulose (E464), titanium dioxide (E171), polydimethyl siloxane, polyethylene glycol 6000 and talc (E553b).

What Lopid looks like and contents of the pack

Lopid 300 mg capsules contain a fine white powder in a hard gelatine capsule with a white opaque body and maroon cap, with 'Lopid 300' imprinted on each capsule half. It is packaged in aluminium foil blister strips containing 20, 60, 100 and 112 capsules.

Lopid 600 mg is a white oval film-coated tablet. It is packaged in transparent PVC blister strips with an aluminium foil back in packs containing 14, 20, 28, 30, 50, 56, 60, 98, 100, 196, 500 and 600 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Pfizer Ltd, Ramsgate Rd, Sandwich, Kent, CT13 9NJ, UK.

Manufacturer
Pfizer Manufacturing Deutschland GmbH
Betriebsstätte Freiburg
Mooswaldallee 1
79090 Freiburg,
Germany.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:
Lopid: Denmark, Greece, Iceland, Ireland, Italy, Netherlands, Portugal, Spain, Sweden and United Kingdom (Northern Ireland)
Gevilon: Austria, Germany
Lipur: France

This leaflet was last revised in 12/2022.

Ref: LP 19_0