

IPOLIPID CAPSULE

Gemfibrozil (300mg)

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What IPOLIPID is used for

IPOLIPID is used to treat hyperlipidaemia (having too much fat in the blood) and to prevent heart disease in people in hyperlipidaemia.

IPOLIPID helps reduce cholesterol and triglycerides (fatty acids) in the blood. High levels of these types of fat in the blood are associated with an increased risk of atherosclerosis (hardening of blood vessels/arteries).

IPOLIPID is also used to lower the risk of stroke, heart attack, or other heart complications in people with high cholesterol and triglycerides who have not responded to dietary and other measures.

How IPOLIPID works

IPOLIPID 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.

Before you use IPOLIPID

- When you must not use it

Do not take IPOLIPID:

- if you are allergic to gemfibrozil or any of the other ingredients of this medicine
- 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

- Before you start to use it

Talk to your doctor or pharmacist before taking IPOLIPID especially if you have any of the following conditions:

- 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 IPOLIPID in combination with statins used to lower cholesterol levels and triglycerides, and increase good cholesterol such as rosuvastatin and simvastatin
- mild or moderate kidney disease
- under-active thyroid
- diabetes

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.

It is recommended that you do not take IPOLIPID while you breastfeed. Ask your doctor or pharmacist for advice before taking this medicine.

- Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

This includes:

- anti-diabetic medication particularly rosiglitazone or repaglinide (used to help reduce blood sugar levels)
- dasabuvir, a drug used to treat hepatitis C infection
- selexipag, a treatment for pulmonary hypertension
- statins used to lower bad cholesterol and triglycerides, and increase good cholesterol such as atorvastatin, lovastatin, pravastatin, rosuvastatin and simvastatin
- dabrafenib, a treatment for melanoma (skin cancer)
- 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

How to use IPOLIPID

- How much to use

Usual adult dose:

Orally 4 capsules (1.2g) a day in two divided doses thirty minutes before the morning and evening meals.

- When to use it

Thirty minutes before the morning and evening meals.

- How long to use it

Continue taking IPOLIPID for as long as your doctor recommends

- If you forget to use it

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 (two doses at the same time) to make up for a forgotten dose.

- If you use too much (overdose)

If you accidentally take too much IPOLIPID contact your doctor at once or go to the nearest hospital accident and emergency department. Always take the labelled medicine package with you.

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you
- Tell all doctors, dentists and pharmacists treating you that you are taking IPOLIPID
- Tell your doctor immediately if you become pregnant while taking this medication

Things you must not do

- Do not pass IPOLIPID to others, even if their signs of illness are the same as yours.
- Do not stop taking IPOLIPID unless your doctor tells you to. It is recommended that you follow all the advice given while you are taking IPOLIPID so as to gain the full benefit of the treatment.

- Things to be careful of

Driving and using machines

In rare cases IPOLIPID may cause dizziness and affect your eyesight, if this

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happens, do not drive or operate machinery.

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 IPOLIPID:

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)

- headache, vertigo (sense of spinning or swaying)
- diarrhoea, vomiting, nausea, stomach pain, constipation, wind
- eczema, rash (particularly an itchy or puffy rash)
- 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), severe anaemia
- depression, decreased libido
- dizziness, sleepiness, numbness on the limbs
- blurred vision
- appendicitis, pancreatitis
- jaundice (yellowing of the skin), disturbed liver function,

inflammation of the liver (hepatitis), gallstones (cholelithiasis), inflammation of the gall bladder (cholecystitis)

- red, itchy raised areas of skin, hair loss, photosensitivity (a sensitivity to light that can cause skin discolouration or a rash), itching, inflammation of the skin or inflamed skin which flakes or falls off
- painful joints and extremities, inflammation of the muscles (myositis), inflammation of the synovial membrane (synovitis), muscle weakness
- impotence
- unusual bruising or bleeding due to a reduction in blood platelets (thrombocytopenia)

You may report any side effects or adverse reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [Public → Reporting Side Effects to Medicines (ConSERF) of Vaccines (AEFI)]

Storage and Disposal of IPOLIPID

- Storage

- Keep this medicine out of sight and reach of children.
- Store below 30°C in the original package.

- Disposal

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

Product description

What it looks like

IPOLIPID 300mg hard gelatin capsules (300mg) are maroon-white, hard gelatin capsules, size "0" printed "IPOLIPID".

- Ingredients

- Active ingredient

The active substance is Gemfibrozil

- Inactive ingredients

The other ingredients are:

sodium starch glycolate, colloidal hydrated silica, pregelatinised maize starch and magnesium stearate.

- MAL number:

MAL19900461AZ

Manufacturer

MEDOCHEMIE LTD. (Factory AZ), 2 Michael Erakleous Street, Agios Athanassios Industrial Area, Agios Athanassios, 4101 Limassol, Cyprus

Product registration holder

KOMEDIC SDN BHD, 4 Jalan PJS 11/14, Bandar Sunway, 46150 Petaling Jaya, Selangor D.E.

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