

PHARMANIAGA GEMFIBROZIL CAPSULE

Gemfibrozil 300mg

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What Pharmaniaga Gemfibrozil Capsule is used for

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

Pharmaniaga Gemfibrozil Capsule 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).

Pharmaniaga Gemfibrozil Capsule 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 Pharmaniaga Gemfibrozil Capsule works

Gemfibrozil belongs to the class of medications known as *fibrates*. It works by lowering the level of certain types of fat and cholesterol, especially the type known as *triglycerides*.

Before you use Pharmaniaga Gemfibrozil Capsule

-When you must not to use it

Do not take Pharmaniaga Gemfibrozil Capsule if you:

- are allergic to any medicine containing gemfibrozil
- are allergic to fenofibrate or any other of the class of "fibrates" (e.g., clofibrate, bezafibrate)
- are breast-feeding
- are pregnant
- have severe liver disease, kidney disease, or gallbladder disease

-Before you start to use it

Tell your pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor or pharmacist can discuss with you the risks and benefits involved.

-Taking other medicines

Tell your pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

If you are taking more than one medicine they may interact with each other. At times your prescriber may decide to use medicines that interact, in other cases this may not be appropriate.

The decision to use medicines that interact depends on your specific circumstances. Your prescriber may decide to use medicines that interact, if it is believed that the benefits of taking the medicines together outweigh the risks. In such cases, it may be necessary to alter your dose or monitor you more closely.

Tell your prescriber the names of all the medicines that you are taking so that they can consider all possible interactions. This includes all the medicines which have been prescribed by your GP, hospital doctor, dentist, nurse, health visitor, midwife or pharmacist. You must also tell your prescriber about medicines which you have bought over the counter without prescriptions.

The following medicines may interact with Gemfibrozil:

- Anticoagulants, Coumarin, Indandione derivative
Concurrent use may significantly increase the blood thinning effect of these medications, your doctor may need to do some blood test to adjust the anticoagulants dose.
- Chenodiol or ursodiol(used to treat gallstone)
Effects may be decreased when used concurrently with gemfibrozil.
- Lovastatin (cholesterol lowering agent)
Concurrent use may be associated with an increase in creatine kinase (CK) concentrations and myoglobinuria(presence of myoglobin in the urine). This leads to acute kidney failure that may be seen as early as 3 weeks or as late as several months after initiation of combined therapy.

If you are taking Gemfibrozil and one of the above medicines or types of medicines, make sure your prescriber knows about it.

Complementary preparations and vitamins

Medicines can interact with complementary preparations and vitamins. In general, there is not much information available about interactions between medicines and complementary preparations or vitamins.

If you are planning to take or are already taking any complementary preparations and vitamins you should ask your prescriber whether there are any known interactions with Gemfibrozil.

Your prescriber can advise whether it is appropriate for you to take combinations that are known to interact. They can also discuss with you the possible effect that the complementary preparations and vitamins may have on your condition.

If you experience any unusual effects while taking this medicine in

combination with complementary preparations and vitamins, you should tell your prescriber.

How to use Pharmaniaga Gemfibrozil Capsule

Follow all directions given to you by your pharmacist or doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the directions on your prescription bottle, ask your pharmacist, nurse, or doctor to explain the instructions to you.

-How much to use

Usual adult dose:

Orally 4 capsules (1.2 g) a day in two divided dose 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 your medicine for as long as your doctor tells you.

It is important to keep taking your medicine even if you feel well. Suddenly stopping your medicine may cause your original condition to return. This is why you must speak to your prescriber if you are having any problems taking your medicine.

Your doctor may withdraw the treatment of Pharmaniaga Gemfibrozil Capsule if the response is inadequate after 3 months or if the results of liver function test show significant abnormalities.

-If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take extra medicine to make up the missed dose.

-If you take too much (overdose)

Contact your doctor or go to your nearest hospital immediately. Do not drive if you have taken too many.

While you are using it

-Things you must do

Talk to your pharmacist or doctor if your symptoms do not improve.

Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

-Things you must not do

Do not take Pharmaniaga Gemfibrozil Capsule to treat any other complaints unless your pharmacist or doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not take more than the recommended dose unless your pharmacist or doctor tells you to.

-Things to be careful of

Be careful driving or operating machinery until you know how Pharmaniaga Gemfibrozil Capsule affects you.

Do not drink alcohol while taking this medication.

Side effects

Tell your pharmacist or doctor if you do not feel well while you are taking Pharmaniaga Gemfibrozil Capsule. This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects. Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your pharmacist doctor to answer any questions you may have.

Everyone's reaction to a medicine is different. It is difficult to predict which side affects you will have from taking a particular medicine, or whether you will have any side effects at all. The important thing is to tell your prescriber or pharmacist if you are having problems with your medicine.

The reported side effects are:

- Stomach pain, gas or heartburn
- diarrhoea

- nausea or vomiting
- skin rash
- tiredness
- anaemia or leucopenia (cough or hoarseness; fever or chills, lower back or side pain, painful or difficult urination)
- gallstones (severe stomach pain with nausea and vomiting)
- myositis (muscle pain, unusual tiredness or weakness)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of Pharmaniaga Gemfibrozil Capsule

-Storage

Keep the medicines in a cool dry place where the temperature stays below 25°C. Protect from light.

Do not store it or any other medicine in the bathroom, or near a sink, or on a window sill.

Do not leave it in the car on hot days. Heat and dampness can destroy some medicines.

Do not use this medication after the expiry date which is printed on the product packaging. The expiry date refers to the last day of that month.

Keep it where children cannot reach it.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

Scarlet/white size '0' hard gelatin capsule with Pharmaniaga icon and '300' markings.

-Ingredients:

-Active ingredient:

Pharmaniaga Gemfibrozil Capsule contains Gemfibrozil 300mg

-Inactive ingredients:

Microcrystalline Cellulose, Lactose
Croscarmellose Sodium, Magnesium
Stearate, Starch and Colloidal Silicon
Dioxide.

-MAL Number:

MAL19972153AZ

Manufacturer:

Pharmaniaga Manufacturing
Berhad (60016-D),
11A, Jalan P/1, Kawasan
Perusahaan Bangi, 43650 Bandar
Baru Bangi, Selangor Darul Ehsan,
Malaysia.

Product Registration Holder:

Pharmaniaga Manufacturing
Berhad (60016-D),
11A, Jalan P/1,
Kawasan Perusahaan Bangi,
43650 Bandar Baru Bangi,
Selangor Darul Ehsan,
Malaysia.

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