

Pharmaniaga Gemfibrozil Capsule 300mg

DESCRIPTION

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

Capsule shell is of bovine source.

COMPOSITION

Each capsule contains Gemfibrozil 300 mg.

ACTIONS

Gemfibrozil is a lipid regulating agent. It reduces plasma triglyceride very low-density lipoprotein (VLDL) concentrations and increases high-density lipoprotein (HDL) concentrations. It also reduces elevated plasma concentrations of cholesterol to a lesser extent but the effect is variable. The mechanism of action is not clear.

Gemfibrozil is readily absorbed from the gastrointestinal tract; peak concentrations in plasma occur within 1 to 2 hours, the half-life is about 1.5 hours. Plasma protein binding of gemfibrozil is about 98%.

INDICATIONS

Gemfibrozil is used in conjunction with dietary modification in the treatment of type IIa, type IIb, type III, type IV and type V hyperlipoproteinaemia. It is also indicated for the primary prevention of ischaemic heart disease in hyperlipidaemic patients who have not responded to dietary and other measures; in the USA this use is restricted to type IIb patients who also have low HDL cholesterol concentrations.

CONTRAINDICATIONS

Gemfibrozil is contraindicated in patients with hepatic or severe renal dysfunction, including primary biliary cirrhosis; in pre-existing gall bladder disease; and in patients who are hypersensitive to the drug.

ADVERSE REACTIONS

Stomach pain, gas or heartburn; diarrhoea, nausea or vomiting, skin rash, unusual 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).

PRECAUTIONS / WARNINGS

Caution is advised in patients with hypoalbuminaemic states such as the nephrotic syndrome.

Pregnancy/Reproduction

Studies in male rats revealed a dose related decrease in fertility.

Studies in female rats given 0.6 to 2 times the human dose (based on surface area) before and throughout gestation resulted in a dose-related decrease in conception rate and an increase in skeletal variations, including anophthalmia. At high dose level an increase in stillbirths and reductions in pup weight during lactation were observed. In addition similar doses given to female rats from gestation day 15 through weaning resulted in decreased birth weights and pup growth suppression during lactation.

Gemfibrozil given at doses 1 to 3 times the human dose (based on surface area) to female rabbits during organogenesis, caused decreased litter size and, at high dose, an increased incidence of parietal bone variations.

Although studies in humans have not been done, gemfibrozil should only be used during pregnancy if the potential benefit justifies the potential risk to the foetus.

Breast-feeding

It is not known whether gemfibrozil is excreted in breast milk. Problems in humans have not been documented; however, any decisions regarding breast-feeding during therapy should take into account that gemfibrozil has tumorigenic effect in rats.

Paediatrics

Appropriate studies on the relationship of age to the effects of gemfibrozil have not been performed. However, use in children under 2 years of age is not recommended since cholesterol is required for normal development.

Geriatrics

No information is available. However, elderly patients are more likely to have age-related renal function impairment, which may require reduction in dosage in patients receiving gemfibrozil.

Monitoring Parameters

Patients should be monitored for complete blood counts, serum lipids, serum cholesterol, serum triglycerides and liver functions tests. Determinations are recommended prior to initiation of therapy and at periodic intervals during therapy.

The drug should be withdrawn if the lipid response with the recommended dosage is inadequate after 3 months. If results of liver function test rise significantly

or show significant abnormalities, it is recommended that gemfibrozil therapy be withdrawn and not resumed; laboratory abnormalities are reversible.

When gemfibrozil is discontinued, an appropriate hypolipidaemic diet and monitoring of serum lipids are recommended until the patient stabilises, since a rise in serum, triglycerides and cholesterol concentrations to the original base may occur.

If gallstones are found, gemfibrozil therapy should be withdrawn. If the patient experience muscle pain or weakness, evaluation for myositis (including serum CK determinations) is recommended. It is recommended that gemfibrozil be withdrawn if myositis is suspected or diagnosed.

DRUG INTERACTIONS

<u>Drug</u>	<u>Effects</u>
1. Anti-coagulants, coumarin or indandione derivative.	Concurrent use may significantly increase the anti-coagulant effect of these medications, adjustment of anti-coagulant dosage based on frequent prothrombin-time determinations is recommended.
2. Chenodiol or ursodiol.	Effect may be decreased when used concurrently with gemfibrozil, which tends to increase cholesterol saturation of bile.
3. Lovastatin.	Concurrent use may be associated with an increase in creatine kinase (CK) concentrations, and myoglobinuria. This leads to acute renal failure that may be seen as early as 3 weeks or as late as several months after initiation of combined therapy; monitoring of CK has not been shown to prevent severe myopathy or renal damage.

DOSAGE AND ADMINISTRATION

Usual adult dose:

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

Usual paediatric dose:

Dosage has not been established.

OVERDOSAGE

There have been reported cases of overdosage with gemfibrozil. In one case a 7 years old child recovered after ingesting up to 9 g of gemfibrozil. Symptomatic supportive measures should be taken should an overdose occurs.

ROUTE OF ADMINISTRATION

Oral.

STORAGE CONDITIONS

Store below 30°C.

Keep container tightly closed.

Protect from light.

SHELF LIFE

Product should not be used beyond the expiry date imprinted on the product packaging.

PRESENTATION

In bottle of 30 capsules (for KKM tender only).

In blisters of 30, 100, 250 and 500 capsules.

Date of revision: 25th June 2024

PRODUCT REGISTRATION HOLDER/MANUFACTURER: PHARMANIAGA MANUFACTURING BERHAD (198001006232)

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