United Pharmaceuticals

LOW-LIP®

Gemfibrozil

Description:

LOW-LIP® (Gemfibrozil) is a lipid-regulating agent, which decreases total serum cholesterol and serum triglycerides. These decreases occur in the low density lipoprotein (LDL) fraction and in the very low density lipoprotein (VLDL) fraction. In addition, LOW-LIP® increases high density lipoprotein (HDL) choles-terol.

Properties:

Gemfibrozil is well absorbed, highly protein bound and mainly metabolized via liver, the main metabolite is a benzoic acid metabolite. Intestinal re-absorption is a significant part of the metabolism of Gemfibrozil. Approximately 70% of Gemfibrozil is eliminated through the kidneys with elimination half-life of 1.4hours.

Indications:

LOW-LIP® is indicated in the treatment of certain lipid metabolic disorders, which are not adequately affected by a change of diet or other external factors such as physical exercise or weight loss. Besides high blood pressure and smoking, an elevated blood lipid level is considered to be one of the major risk factors leading to the occurrence and progression of atherosclerosis.

LOW-LIP® also may be used in Lipid metabolic dis-orders which may occur in association with diseases such as diabetes, gout or other diseases which pers-ist despite control of the underlying disease.

Dosage and administration:

One tablet LOW-LIP® twice daily in the morning and evening, 30 minuts before meals.

Contraindications:

Hypersensitivity to Gemfibrozil.

Alcoholism, severe renal or hepatic dysfunction in-cluding primary biliary cirrhosis and pre-existing gall bladder disease with or without gall stone.

Precautions:

Serum lipids should be controlled before starting Gemfibrozil therapy, with appropriate diet, exercise, cessation of smoking, limitation of alcohol intake, weight loss in obese patients and treatment of the causes of secondary hyperlipidaemias such as hypo-thyroidism and diabetes mellitus.

Therapy monitoring and adequate pretreatment la-boratory tests should be performed.

Use during pregnancy and lactation:

Use during pregnancy only when the benefit clearly outweighs the possible risk to the mother or fetus.

Discontinue either nursing or drug therapy, taking in-to account the importance of the drug to the mother.

Drug interactions:

•Anticoagulants: Gemfibrozil may enhance the phar-macological effects of these agents.

•Estrogen oral contraceptives: Inform your physician if you are taking oral contraceptive pills because it may be the reason of your dyslipidemia.

•Lovastatin and other HMG-CoA reductase inhibitors: Severe myositis has occurred with combined Gemfi-brozil and Lovastatin therapy. Therefore, they should not be used concomi-tantly.

•Cyclosporin levels may be reduced upon concurrent therapy with Gemfibrozil.
•Rifampin may decrease Gemfibrozil levels.
•Reduced bioavailability of Gemfibrozil may result when given simultaneously with resin-granule drugs such as Colestipol. Administration of the drugs two hours or more apart is recommended.

Side effects:

Usually transient Gastrointestinal complaints which include: Dyspepsia,abdominal pain, di-arrhea, nausea, epigastric pain, vomiting and flatulence.
Rare cases: headache, dermatitis, blurred vision, fa-tigue and vertigo.
Cases of transaminase increases and painful ex-tremities and myalgia.

Overdosage:

Overdosage has been reported with Gemfibrozil. Symptoms reported with overdosages were abdo-minal cramps, abnormal liver function tests, diarrhea, increased creatine phosphoki-nase, joint and muscle pain, nausea and vomiting.
Symptomatic supportive measures should be taken should overdose occur.

Storage conditions:

Store between 15- 30ºC.

Presentation:

LOW-LIP® 600 Tablets: Each film coated tablet contains Gemfibrozil 600 mg in packs of 30 tablets.
Hospital packs are also available.

Excipients:-

- Colloidal silicon dioxide, Polysorbate 80, Hydroxypropyl cellulose, Pregelatinized starch, Dibasic calcium phosphate, Microcrystalline cellulose, Croscarrnelose sodium, Magnesium Stearate & Opadry white.

This is a medicament

• Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
• Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
• The doctor and the pharmacist are experts in medicine, its benefits and risks.
• Do not by yourself interrupt the period of treatment prescribed for you.
• Do not repeat the same prescription without consulting your doctor.
• Keep medicament out of the reach of children.

COUNCIL OF ARAB HEALTH MINISTERS
UNION OF ARAB PHARMACISTS

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