



# Lipomid® (Simvastatin)

## Properties:

**Lipomid®** is a blood lipid lowering agent belonging to HMG-CoA inhibitors. After oral intake of **Lipomid®** it is hydrolyzed to its active  $\beta$ -hydroxyacid form. This is a competitive inhibitor of 3-hydroxy-3-methylglutaryl coenzyme A reductase (HMG-CoA reductase inhibitor), so inhibits the biosynthesis of cholesterol. **Lipomid®** undergoes extensive first-pass metabolism in the liver, its primary site of action, and only few amount of the drug reaches the general circulation as active inhibitors. **Lipomid®** is effective in reducing total and LDL cholesterol in patients with primary hypercholesterolemia.

## Indications:

**Lipomid®** is indicated as adjunct to diet to reduce total cholesterol, Low Density Lipoprotein (LDL) cholesterol, and Triglyceride (TG) levels in patients with primary hypercholesterolemia and mixed dyslipidemia. **Lipomid®** also used to reduce the risk of total morbidity in patients with coronary heart disease with hypercholesterolemia.

## Side effects:

The frequency of side effects occurring is mild and drug related, including gastro-intestinal disturbances, headache, skin rashes, dizziness, myopathy has been reported rarely, liver function test abnormalities have been generally mild and transient.

## Contraindications:

Hypersensitivity to any of the components. Simvastatin should not be given to patients with acute liver disease or unexplained persistent raised serum-aminotransferase concentrations. It should be avoided during pregnancy and lactation.

## Warnings:

Simvastatin and other HMG-CoA inhibitors may cause myopathy, which appears as muscle pain and this is associated with grossly elevated creatine kinase.

## Precautions:

Due to its effect on liver enzymes, liver function tests should be performed before and during treatment in a regular pattern. Simvastatin may cause elevation of creatine kinase and transaminase levels and special attention should be taken in consideration. This enzyme elevation should be considered in the differential diagnosis of chest pain in patients on therapy with simvastatin.

## Dosage and Administration:

The patient should follow a standard cholesterol-lowering diet even when he is under medication. **Lipomid®** is given by mouth in an initial dose of 10 mg at night. The dose may be adjusted at intervals of not less than 4 weeks up to a maximum of 40 mg once daily at night. If total plasma cholesterol levels fall below 3.5 mmol/l, consideration should be taken to reduce the dose. **Lipomid®** is used alone or with bile acid sequestrants, in this case **Lipomid®** should be taken one hour before or four hours after the resins in order to prevent decrease in absorption. No need for dosage adjustment in case of renal insufficiency.

## Presentations:

- Lipomid®** 10: Simvastatin U.S.P. 10 mg/ film coated tablet, pack of 10 and 30 tablets.  
**Lipomid®** 20: Simvastatin U.S.P. 20 mg/ film coated tablet, pack of 10 and 30 tablets.

### This is a medicament

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, method of use and the instructions of 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 prescription without consulting your doctor.

Manufactured By: Middle East Pharmaceutical Company - Midpharma - Jordan

PI023

A / E

Rev. 09 / 00