

Rosuvastatin

Lipichek

10 mg Film-Coated Tablet
20 mg Film-Coated Tablet
ANTHYPERLIPIDAEMIC

FORMULATION:

Each film-coated tablet contains:

Rosuvastatin (as calcium).....10 mg
Rosuvastatin (as calcium).....20 mg

PHARMACOKINETICS:

Rosuvastatin is incompletely absorbed from the gastrointestinal tract, with bioavailability of about 20%. Peak plasma concentrations are achieved about 5 hours after an oral dose. It is taken up extensively by the liver, its primary site of action, and undergoes limited metabolism, mainly by the cytochrome P450 isoenzyme CYP2C9. It is about 90% bound to plasma proteins. The plasma elimination half-life of rosuvastatin is about 19 hours. About 19% of oral dose of rosuvastatin is excreted in the faeces, including absorbed and non-absorbed drug and the remainder is excreted in the urine; about 5% of a dose is excreted unchanged in urine.

INDICATIONS:

For primary hypercholesterolemia (Type II a including heterozygous familial hypercholesterolemia), mixed dyslipidemia (Type II b), or homozygous familial hypercholesterolemia in patients who have not responded adequately to diet and other appropriate measures.

CONTRAINDICATIONS:

Rosuvastatin is contraindicated in patients with a known hypersensitivity to any component of this product. It is contraindicated in patients with active liver disease or with unexplained persistent elevations of serum transaminases.

DRUG INTERACTIONS:

Rosuvastatin undergoes limited metabolism, principally by the cytochrome P450 isoenzyme CYP2C9 and may not have the same interactions with enzyme inhibitors as simvastatin. However, increased rosuvastatin plasma concentrations have been reported with ciclosporin and to a lesser extent with gemfibrozil, and such combination should be avoided. If they must be given together, lower doses of rosuvastatin should be used.

ADVERSE EFFECTS:

The most common adverse effects of therapy with rosuvastatin and other statins are gastrointestinal disturbances. Other adverse effects reported include headache, skin rashes, dizziness, blurred vision, insomnia, dysgeusia. Reversible increases in serum-aminotransferase concentration may occur and liver function should be assessed before treatment is initiated and then monitored periodically until one year after the last elevation in dose. Hepatitis and pancreatitis have been reported. Myopathy, characterized by myalgia, and muscle weakness and associated with increased creatinine phosphokinase concentration has been reported, especially in patients taking rosuvastatin concurrently with ciclosporin, fibric acid derivatives or nicotinic acid. Rarely, rhabdomyolysis with acute renal failure may develop.

PRECAUTIONS:

Rosuvastatin should not be given to patients with acute liver disease or unexplained persistently raised serum-aminotransferase concentrations. It should be avoided during pregnancy since there is a possibility that it could interfere with fetal sterol synthesis; there have been a few reports of congenital abnormalities associated with statins. It should be discontinued if marked or persistent increases in serum-aminotransferase or creatine phosphokinase concentrations occur. It should be used with caution in patients with severe renal impairment.

DOSAGE AND ADMINISTRATION:

Usual initial dose is 10 mg once daily. However, a lower initial dose of 5 mg once daily may be adequate and is also recommended for patients at risk of myopathy. Patients with marked hypercholesterolaemia, such as those with homozygous familial hypercholesterolaemia, may be started on 20 mg once daily. Or as prescribed by the physician.

AVAILABILITY:

Rosuvastatin 10 mg FC Tablet Packed in Alu-alu foil, (Box of 30's).
Rosuvastatin 20 mg FC Tablet Packed in Alu-alu foil, (Box of 30's).

CAUTION:

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORE AT TEMPERATURES NOT EXCEEDING 30°C.

Manufactured by :

PSA INTERNATIONAL
(Export Div. of PSA Chemicals &
Pharmaceuticals Pvt. Ltd.)
Vashi, Navi Mumbai, INDIA.

Imported by :

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cor. Export Bank Drive, Makati City, PHILIPPINES.

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