

### Composition

**Rosulux 5 Tablet:** Each film coated tablet contains Rosuvastatin Calcium BP equivalent to Rosuvastatin 5 mg.

**Rosulux 10 Tablet:** Each film coated tablet contains Rosuvastatin Calcium BP equivalent to Rosuvastatin 10 mg.

**Rosulux 20 Tablet:** Each film coated tablet contains Rosuvastatin Calcium BP equivalent to Rosuvastatin 20 mg.

### Pharmacology

Rosuvastatin calcium is a synthetic lipid lowering agent. Rosuvastatin is an inhibitor of 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methylglutaryl coenzyme A to mevalonate, a precursor of cholesterol.

### Indication

- Adult patients with primary hyperlipidemia and mixed dyslipidemia as an adjunct to diet to reduce elevated total-C, LDL-C, ApoB, nonHDL-C and TG levels and to increase HDL-C.
- Pediatric patients 8 to 17 years of age with heterozygous familial hypercholesterolemia (HeFH) to reduce elevated total-C, LDL-C and ApoB after failing an adequate trial of diet therapy.
- Pediatric patients 7 to 17 years of age with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C, total-C, nonHDL-C and ApoB as an adjunct to diet, either alone or with other lipid-lowering treatments.
- Adult patients with hypertriglyceridemia as an adjunct to diet
- Adult patients with primary dysbetalipoproteinemia (Type III hyperlipoproteinemia) as an adjunct to diet.
- Adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C, total-C and ApoB.
- Slowing the progression of atherosclerosis as part of a treatment strategy to lower total-C and LDL-C as an adjunct to diet.
- Risk reduction of MI stroke and arterial revascularization procedures in patients without clinically evident CHD but with multiple risk factors.

### Dose & administration

a) *Route of administration:* Oral

- Dose range: 5-40 mg once daily. Use 40 mg dose only for patients not reaching LDL-C goal with 20 mg.
- Adult HoFH: Starting dose 20 mg/day.
- Pediatric patients with HeFH: 5 to 10 mg/day for patients 8 to less than 10 years of age and 5 to 20 mg/day for patients 10 to 17 years of age.
- Pediatric patients with HoFH: 20 mg/day for patients 7 to 17 years of age.

### Contra-indication

Rosuvastatin is contraindicated if-

- Known hypersensitivity to product components.
- Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels.
- Pregnant women and women who may become pregnant.
- Nursing mothers.

### Warning and Precaution

Rosuvastatin should be prescribed with caution in patients with predisposing factors for myopathy (e.g., age>65 years, inadequately treated hypothyroidism, renal impairment). The risk of myopathy during treatment with rosuvastatin may be increased with concurrent administration of some other lipid lowering therapies (Fibrates or Niacin).

### Side effects

a) *Common:* Rosuvastatin is generally well tolerated. The adverse events seen with Rosuvastatin are generally mild and transient. Most commonly occurring side-effects are headache, myalgia, asthenia, constipation, dizziness, nausea, abdominal pain. Pruritus, rash and urticaria may occur.

b) *Rare:* Myopathy (including myositis), hypersensitivity reactions (including angioedema), rhabdomyolysis, pancreatitis etc are the rarely occurring side-effects of Rosuvastatin.

### Use in Special Population

Age and sex: There was no clinically relevant effect of age or sex on the pharmacokinetics of Rosuvastatin in adults.

Severe renal impairment (not on hemodialysis): Starting dose is 5 mg, not to exceed 10 mg.

### Use in Pregnancy & Lactation

*Pregnancy:* Rosuvastatin should be administered to women of childbearing age and have been informed of potential hazards.

*Lactation:* It is not known whether rosuvastatin is excreted in human milk, but small amount of other drug in this class does pass into breast milk.

### Use in Children & Adolescents

See the dose and administration

### Drug Interaction

a) *With medicine:* Remarkable drug interactions of Rosuvastatin are-

- Cyclosporine: Combination increases Rosuvastatin exposure. Rosuvastatin dose should be limited to 5 mg once daily.
- Gemfibrosil: Combination should be avoided. If used together, Rosuvastatin dose should be limited to 10 mg once daily.
- Lopinavir/Ritonavir or atazanavir/ritonavir: Combination increases Rosuvastatin exposure. Rosuvastatin dose should be to 10 mg once daily.
- Coumarin anticoagulants: Combination prolongs international normalized ratio (INR). Stable INR should be achieved prior to starting Rosuvastatin. INR should be monitored frequently until stable upon initiation or alteration of Rosuvastatin therapy.
- Concomitant lipid-lowering therapies: Use with fibrates and niacin products may increase the risk of skeletal muscle effects.

b) *With food & other:* Avoid eating foods high in fat or cholesterol or rosuvastatin will not be as effective. Avoid drinking alcohol it can rise triglyceride levels and may increase the risk of liver.

### Overdose

There is no specific treatment in the event of overdose. In the event of overdose, the patient should be treated symptomatically and supportive measures instituted as required. Hemodialysis is unlikely to be of benefit.

### Storage

Store below 30°C. Protect from light and moisture. Keep all medicines out of reach of children.

### Packing

**Rosulux 5 tablet:** Each box contains 30 (3x10's) tablets in blister pack.

**Rosulux 10 tablet:** Each box contains 20 (2x10's) tablets in blister pack.

**Rosulux 20 tablet:** Each box contains 20 (2x10's) tablets in blister pack.