



**HIGHLIGHTS OF PRESCRIBING INFORMATION**  
These highlights do not include all the information needed to use ROSUVASTATIN TABLETS, safely and effectively. See full prescribing information for ROSUVASTATIN TABLETS.  
**ROSUVASTATIN tablets, for oral use**  
Initial U.S. Approval: 2003

- Indications and Usage (1)** 07/2024
- INDICATIONS AND USAGE**
- Rosuvastatin tablet is an HMG Co-A reductase inhibitor used to:
- To reduce the risk of major adverse cardiovascular (CV) events (CV death, nonfatal myocardial infarction, nonfatal stroke, or an arterial revascularization procedure) in adults without established coronary heart disease who are at increased risk of CV disease based on age, high-sensitivity C-reactive protein (hsCRP)  $\geq 2$  mg/L, and at least one additional CV risk factor.
  - As an adjunct to diet to:
  - reduce LDL-C in adults with primary hyperlipidemia,
  - reduce LDL-C and slow the progression of atherosclerosis in adults,
  - reduce LDL-C in adults and pediatric patients aged 8 years and older with heterozygous familial hypercholesterolemia (HeFH).
  - As an adjunct to other LDL-C-lowering therapies, or alone if such treatments are unavailable, to reduce LDL-C in adults and pediatric patients aged 7 years and older with homozygous familial hypercholesterolemia (HoFH).
  - As an adjunct to diet for the treatment of adults with:
  - Primary dysoposterolemia.
  - Hypertriglyceridemia.

**DOSEAGE AND ADMINISTRATION**

Take orally with or without food, at any time of day. (2.1)

Assess LDL-C when clinically appropriate, as early as 4 weeks after initiating rosuvastatin tablets, and adjust dosage if necessary. (2.1)

Adults: Recommended dosage range is 5 to 40 mg once daily. (2.1)

Pediatric Patients with HeFH: Recommended dosage range is 5 to 10 mg once daily for patients aged 8 to less than 10 years of age, and 5 to 20 mg once daily for patients aged 10 years and older. (2.2)

Pediatric Patients with HoFH: Recommended dosage is 20 mg once daily for patients aged 7 years and older. (2.2)

Adult Patients: Initiate at 5 mg once daily. Consider risks and benefits of treatment if not adequately controlled at doses up to 20 mg once daily. (2.4)

Patients with Severe Renal Impairment (not on hemodialysis): Initiate at 5 mg once daily and do not exceed 10 mg once daily. (2.5)

See full prescribing information for rosuvastatin tablet dosage and administration modifications due to drug interactions. (2.6)

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#### FULL PRESCRIBING INFORMATION

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