



## Roszet (rosuvastatin/ezetimibe) – New drug approval

- On March 23, 2021, the [FDA approved](#) Althera Pharmaceuticals' [Roszet \(rosuvastatin/ezetimibe\)](#), in adults: as an adjunct to diet in patients with primary non-familial hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C) and alone or as an adjunct to other LDL-C-lowering therapies in patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.
- Roszet is a combination tablet containing [rosuvastatin](#), an HMG CoA-reductase inhibitor (statin), and [ezetimibe](#), a dietary cholesterol absorption inhibitor. Both components are available generically.
- The approval of Roszet was based on previous efficacy data with rosuvastatin and ezetimibe.
- Roszet is contraindicated in patients with:
  - Acute liver failure or decompensated cirrhosis
  - Hypersensitivity to rosuvastatin, ezetimibe, or any excipients in Roszet. Hypersensitivity reactions including anaphylaxis, angioedema, and erythema multiforme have been reported.
- Warnings and precautions for Roszet include myopathy and rhabdomyolysis, immune-mediated necrotizing myopathy, hepatic dysfunction, proteinuria and hematuria, and HbA1c and glucose levels.
- The most common adverse reactions (> 2% and greater than statin alone) with ezetimibe co-administered with a statin are nasopharyngitis, myalgia, upper respiratory tract infection, arthralgia, diarrhea, back pain, influenza, pain in extremity, and fatigue.
- The recommended dosage range of Roszet is 5 mg/10 mg to 40 mg/10 mg once daily.
  - The recommended dose of Roszet depends on a patient's indication for usage, LDL-C, and individual risk for cardiovascular events.
  - The starting dosage for patients switching to Roszet from co-administration of a statin and ezetimibe is based on an equivalent dose of rosuvastatin and 10 mg of ezetimibe.
- Althera Pharmaceuticals launch plans for Roszet are pending. Roszet will be available as a 5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg, and 40 mg/10 mg tablets.



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