

# Now Available: Generic Ezetimibe-Rosuvastatin Combination Tablets - In A Trial, 80% Of CHD Patients Reached LDL-C goal

*Generic cost of \$5 to \$25 for most patients -- ezetimibe-rosuvastatin tablets is a generic version of Roszet (rosuvastatin and ezetimibe) tablets*

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We are excited to have a new option available to patients who can now get a powerful LDL-C reduction therapy at a very affordable price."

*Sanjeev Agarwal, CEO of Althera Pharmaceuticals*

Significantly more patients with coronary heart disease had their bad cholesterol controlled to below 70 mg/dL on ezetimibe-rosuvastatin 10 mg-40 mg vs. highest dose (40 mg) of rosuvastatin.

Althera Pharmaceuticals, a company focused on heart health, today announced the commercial availability of [generic ezetimibe-rosuvastatin tablets](#). This product is a generic version of the company's [Roszet](#) (rosuvastatin and ezetimibe) tablets which is FDA approved for treatment of elevated low-density lipoprotein cholesterol (LDL-C), as an

adjunct to diet, in adult patients with primary non-familial hyperlipidemia and, alone or as an adjunct to other LDL-C lowering therapies, in adult patients with homozygous familial hypercholesterolemia. This combination contains rosuvastatin, a powerful statin for LDL-C reduction, and ezetimibe, an efficacious cholesterol absorption inhibitor. The two components work through distinct but complementary mechanisms to significantly lower LDL-C.

As a generic therapy, ezetimibe-rosuvastatin is available to patients at an affordable price. It is available with a generic co-pay of \$5 to \$25 for commercially insured patients. Patients, including those without commercial insurance (Medicare, uninsured etc.), can get it for as little as \$15 to \$25 using GoodRx in major pharmacies.

"We are excited to have a new option available to patients who can now get a powerful LDL-C reduction therapy at a very affordable price. As a company we believe that all patients should be able to get to their cholesterol goals and this product lowers another barrier to heart health," said Sanjeev Agarwal, CEO of Althera Pharmaceuticals. "With an effective LDL-C therapy that is now affordable for a wide range of patients, we are poised to have a positive impact on the health of patients at risk for cardiovascular disease."

## Roszet Indications, Dosage and Other Select Information

Roszet is indicated, as an adjunct to diet, in adults 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 adults with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

Roszet is available as a once-daily tablet with rosuvastatin/ezetimibe dosages of 5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg and 40 mg/10 mg.

Roszet has the potential to reduce LDL cholesterol by as much as 72% with the 40 mg/10 mg dose and by 64% with 10 mg/10mg dose. This level of LDL-reduction derives from both the statin component, rosuvastatin, which can reduce LDL cholesterol by 63% on the highest dose and 52% on 10 mg dose, and the ezetimibe component, which gives an 25% incremental LDL drop when added to statins.

## Roszet Important Safety Information

**Contraindications:** ROSZET is contraindicated in patients with active liver disease or decompensated cirrhosis, and hypersensitivity to any component of this product.

**Use in Specific Populations:** Discontinue Roszet when pregnancy is recognized as it may cause fetal harm. Breastfeeding is not recommended during treatment with Roszet.

**Warnings and Precautions:** Myopathy and rhabdomyolysis may occur with Roszet. Acute kidney injury secondary to myoglobinuria and rare fatalities have occurred as a result of rhabdomyolysis with statins, including rosuvastatin. Discontinue Roszet if markedly elevated CK levels occur or myopathy is diagnosed or suspected. Asian patients on ROSZET may be at higher risk for myopathy. Instruct patients to promptly report any unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

There have been rare reports of IMNM, an autoimmune myopathy, associated with statin use. Increases in serum transaminases have occurred with rosuvastatin. Promptly discontinue Roszet if serious hepatic injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs. Increases in HbA1c and fasting serum glucose levels have been reported with statins, including rosuvastatin.

**Adverse Reactions:** Most frequent adverse reactions for rosuvastatin in clinical trials are headache, nausea, myalgia, asthenia, dizziness, constipation, and abdominal pain. For ezetimibe co-administered with a statin most frequent adverse reactions are nasopharyngitis, myalgia, upper respiratory tract infection, arthralgia, diarrhea, back pain, influenza, pain in extremity, and fatigue.

**Drug Interactions:** Concomitant use of Roszet with gemfibrozil, cyclosporin and antivirals should be avoided. Roszet dose should be limited with darolutamide and regorafenib, risk and benefits should be considered with fenofibrates, niacin and colchicine and INR monitored with initiation or dose adjustment with warfarin.

Please review Important Safety Information and full [Prescribing Information](#) available at [roszet.com](http://roszet.com) for more details on the risks with using Roszet.

#### About Althera

Althera is a privately held pharmaceutical company located in Morristown, NJ. Althera is focused on advancing Heart Health and is committed to providing doctors and their patients important options for treating cardiovascular disease. Althera, along with its partners, has launched the rosuvastatin and ezetimibe combination in 25 countries in Europe and is working on additional launches across the world. For more information visit [www.altherapharma.com](http://www.altherapharma.com).

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Please see full prescribing information for Roszet® (rosuvastatin and ezetimibe) at [www.roszet.com/pi](http://www.roszet.com/pi)

Please contact Althera Pharmaceuticals at [contact@altherainc.com](mailto:contact@altherainc.com)

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