



## CRESTOR<sup>®</sup> (rosuvastatin calcium) Fact Sheet

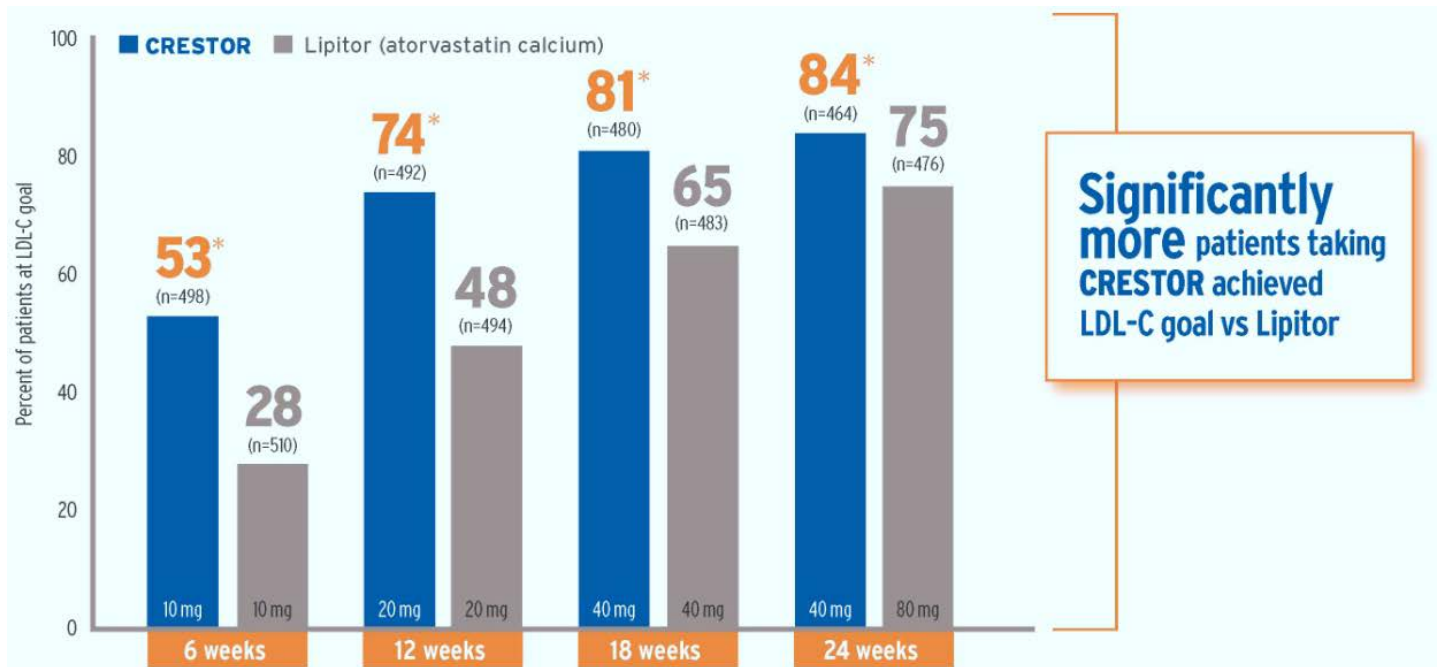
**CRESTOR<sup>®</sup>** (rosuvastatin calcium), a once-daily prescription statin medication, is approved to lower LDL-C and slow the progression of atherosclerosis.<sup>1</sup>

### CRESTOR effectively lowers LDL-C (bad) cholesterol<sup>1</sup>

- In a 6-week multicenter, double-blind, placebo-controlled, dose-ranging study in patients with hyperlipidemia, CRESTOR 5-40 mg has been shown to provide a 45%-63% reduction in LDL-C
  - In fact, CRESTOR has been proven to lower LDL cholesterol by more than half—up to 52%—at its 10 mg starting dose versus 7% with placebo
- CRESTOR is contraindicated in patients with a known hypersensitivity to any component of this product, in patients with active liver disease, and in women who are pregnant, nursing, or could become pregnant<sup>1</sup>

In the ECLIPSE trial, CRESTOR helped more high-risk patients achieve LDL-C goal than Lipitor<sup>®2</sup>

High-risk patients (%) achieving NCEP ATP III LDL-C goal <100 mg/dL<sup>2</sup>



CRESTOR 40 mg should only be used for those patients not achieving their LDL-C goal with 20 mg

Adapted from the ECLIPSE trial.<sup>2</sup> ECLIPSE was a 24-week, open-label, randomized, multicenter, forced-titration, parallel-group trial comparing the efficacy and safety of CRESTOR and atorvastatin in 1036 patients with hypercholesterolemia and CHD, 10-year CHD risk score >20% (CHD risk equivalent), or clinical evidence of atherosclerosis. Following a 6-week dietary lead-in period, patients were randomized to receive CRESTOR 10 mg or atorvastatin 10 mg for 6 weeks. Doses were force-titrated at 6-week intervals until maximum doses were achieved. Statistical comparisons were not made across the dose range, only across the same time period. The primary end point was percentage of patients achieving NCEP ATP III LDL-C goal of <100 mg/dL at Week 24.

## **CRESTOR is also indicated to slow the progression of plaque buildup in arteries, known as atherosclerosis<sup>1</sup>**

- CRESTOR is FDA-approved to slow the progression of [atherosclerosis](#) in patients with elevated cholesterol as part of a treatment strategy to lower total-C and LDL-C to goal. This indication is based largely on the results of a pivotal study called METEOR (**M**asuring **E**ffects on intima media **T**hickness: an **E**valuation **O**f **R**osuvastatin)<sup>1</sup>
- METEOR measured the effects of CRESTOR on plaque-buildup in the carotid arteries using B-mode ultrasonography to measure carotid intima-media thickness (CIMT). Results demonstrated a slowing of progression of atherosclerosis in people taking CRESTOR 40 mg with elevated LDL-C, at low risk (Framingham risk <10% over 10 years) for symptomatic coronary artery disease and with subclinical atherosclerosis<sup>1,3</sup>
  - CRESTOR 40 mg should only be used for those patients not achieving their LDL-C goal with 20 mg.

**METEOR and ECLIPSE are part of the GALAXY Program**—The extensive, long-term, AstraZeneca global research initiative which investigated important unanswered questions in statin research.

### **Accessibility and affordability for CRESTOR**

- CRESTOR has preferred coverage on more Commercial and Medicare Part D health plans than any other branded cholesterol medicine
  - Based on Tier 1, Tier 2 and Preferred Tier 3 coverage status, as of January 2, 2013: Fingertip Formulary<sup>®</sup> Database (last accessed January 2, 2013)
- For commercially insured patients, the CRESTOR Savings Card\* offers eligible patients savings on out-of-pocket costs that exceed \$18 (up to a \$50 savings limit) on each 30-day supply of CRESTOR. The savings card can be used immediately and requires no activation.
  - Patients with no prescription coverage may receive \$50 off the total cost per 30-day supply of CRESTOR.

\*Subject to eligibility. Restrictions apply. See eligibility criteria below.

### **CRESTOR has been approved in the US since 2003, and has received regulatory approval in more than 100 countries worldwide<sup>4</sup>**

- The safety and efficacy of CRESTOR has been studied in over 120 ongoing and completed clinical trials among 67,000 patients worldwide over the past 13 years<sup>4</sup>

Please see Important Safety Information for CRESTOR below. For more information about prescription only CRESTOR, including the full [Prescribing Information](#), call 1-800-CRESTOR or visit [CRESTOR.com](#)

### **About CRESTOR<sup>®</sup> (rosuvastatin calcium) Tablets**

CRESTOR is indicated as an adjunct to diet to reduce elevated total-C, LDL-C, ApoB, non-HDL-C, and triglycerides, and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia and to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower total-C and LDL-C to target levels.

CRESTOR is indicated to reduce the risk of myocardial infarction, stroke, and arterial revascularization procedures in patients without clinically evident coronary heart disease but with an increased risk of cardiovascular disease (CVD) based on age (men  $\geq 50$  and women  $\geq 60$ ), high-sensitivity C-reactive protein (hsCRP)  $\geq 2$  mg/L, and the presence of at least one additional CVD risk factor, such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease.

### **Important Safety Information about CRESTOR**

CRESTOR is contraindicated in patients with a known hypersensitivity to any component of this product, in patients with active liver disease, which may include unexplained persistent elevations of hepatic transaminase levels, in women who are pregnant or may become pregnant, and in nursing mothers.

Cases of myopathy and rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported with statins, including CRESTOR. These risks can occur at any dose level, but are increased at the highest dose (40 mg).

CRESTOR should be prescribed with caution in patients with predisposing factors for myopathy (eg, age  $\geq 65$  years, inadequately treated hypothyroidism, renal impairment). The risk of myopathy during treatment with CRESTOR may be increased with concurrent administration of some other lipid-lowering therapies (fibrates or niacin), gemfibrozil, cyclosporine, lopinavir/ritonavir, or atazanavir/ritonavir.

Therapy with CRESTOR should be discontinued if markedly elevated CK levels occur or myopathy is diagnosed or suspected. There have been rare reports of immune-mediated necrotizing myopathy associated with statin use. All patients should be advised to promptly report unexplained muscle pain, tenderness, or weakness, particularly if accompanied by malaise or fever, and if muscle signs and symptoms persist after discontinuing CRESTOR.

### Important Safety Information about CRESTOR (Cont'd)

It is recommended that liver enzyme tests be performed before the initiation of CRESTOR and if signs or symptoms of liver injury occur. All patients treated with CRESTOR should be advised to promptly report any symptoms that may indicate liver injury, including fatigue, anorexia, right upper abdominal discomfort, dark urine, or jaundice. There have been rare postmarketing reports of fatal and non-fatal hepatic failure in patients taking statins, including CRESTOR. If serious liver injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs during treatment with CRESTOR, promptly interrupt therapy. If an alternate etiology is not found, do not restart CRESTOR.

CRESTOR should be used with caution in patients who consume substantial quantities of alcohol and/or have a history of chronic liver disease.

Increases in HbA1c and fasting serum glucose levels have been reported with statins, including CRESTOR.

In the controlled clinical trials database, the most common adverse reactions were headache (3.7%), myalgia (3.1%), abdominal pain (2.6%), asthenia (2.5%), and nausea (2.2%).<sup>1,5</sup>

Rare postmarketing reports of cognitive impairment (eg, memory loss, forgetfulness, amnesia, memory impairment, confusion) have been associated with statin use, including CRESTOR. These reports are generally nonserious and reversible upon statin discontinuation.

The dose range for CRESTOR is 5 mg to 40 mg orally once daily. The usual starting dose is 10 mg to 20 mg. Patients initiating CRESTOR therapy or switching from another statin should begin treatment with CRESTOR at the appropriate starting dose. After initiation or upon titration of CRESTOR, lipid levels should be analyzed within 2 to 4 weeks and the dosage adjusted accordingly. CRESTOR 40 mg should be used only for those patients not achieving their LDL-C goal with 20 mg.

Please see full [Prescribing Information](#).

If you have any questions concerning CRESTOR, please visit [CRESTOR.com](http://CRESTOR.com) or contact AstraZeneca at 1-800-CRESTOR.

#### \*Patient Eligibility for Savings Card:

**ELIGIBILITY:** This offer is good for eligible patients purchasing at least a 30-day supply of CRESTOR<sup>®</sup> (rosuvastatin calcium) Tablets and may not be used for any other product. This offer is good for the purchase of CRESTOR manufactured for AstraZeneca Pharmaceuticals LP and lawfully purchased from an authorized retailer or distributor in the United States or its territories. This offer is not insurance and is not valid for mail order or prescriptions purchased under Medicaid, Medicare or similar federal or state programs or for patients who are Medicare eligible and enrolled in an employer-sponsored group waiver health plan or government-subsidized prescription drug benefit program for retirees. Offer not valid where prohibited by law, taxed or restricted. Offer is not transferable, is limited to one per person and may not be combined with any other offer. Offer must be presented along with a valid prescription for CRESTOR at the time of purchase.

**OFFER:** If you have commercial insurance for your prescription and your co-pay is more than \$18, you will pay the first \$18 per 30-day supply and receive up to \$50 in savings per 30-day supply. If you pay cash for your prescription, you will receive up to \$50 in savings on your out-of-pocket costs per 30-day supply. **This offer is good for 30-day supply, 60-day supply or 90-day supply and expires 14 months from the date of first use.** If you have any questions regarding this offer, please call 1-888-729-4100. AstraZeneca reserves the right to change or discontinue this offer at any time without notice.

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#### About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialization of prescription medicines for gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide.

For more information about AstraZeneca in the U.S. or our AZ&Me™ Prescription Savings programs, please visit: [www.astrazeneca-us.com](http://www.astrazeneca-us.com) or call 1-800-AZandMe (292-6363).

CRESTOR is a registered trademark, and AZ&Me is a trademark of the AstraZeneca group of companies. LIPITOR is a registered trademark of Pfizer Inc.

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<sup>1</sup> Prescribing Information for CRESTOR. AstraZeneca Pharmaceuticals LP, Wilmington, DE.

<sup>2</sup> Faergeman O, Hill L, Windler E, et al; on behalf of the ECLIPSE study investigators. Efficacy and tolerability of rosuvastatin and atorvastatin when force-titrated in patients with primary hypercholesterolemia. *Cardiology*. 2008;111:219-228.

<sup>3</sup> Crouse JR, Raichlen JS, Riley WA, et al. Effect of Rosuvastatin on Progression of Carotid Intima-Media Thickness in Low-Risk Individuals With Subclinical Atherosclerosis (METEOR Trial). *JAMA*. 2007;297(12); [1344-1353].

<sup>4</sup> Data on File, 2271001, AstraZeneca Pharmaceuticals LP.

<sup>5</sup> Data on File, 268255, AstraZeneca Pharmaceuticals LP.