

Prescribing Information

CRESTOR®

Consult Summary of Product Characteristics (SmPC) before prescribing

Use In patients unresponsive to diet and other non-pharmacological measures, CRESTOR is indicated for primary hypercholesterolaemia (including heterozygous familial hypercholesterolaemia), homozygous familial hypercholesterolaemia, or mixed dyslipidaemia.

Presentation CRESTOR is supplied as film-coated tablets containing 5mg, 10mg, 20mg, or 40mg of rosuvastatin.

Dosage and administration The recommended starting dose for all patients (including those being switched from other statins) is CRESTOR 5 or 10mg once daily. The choice of start dose should take into account the patient's cholesterol level and future cardiovascular risk as well as the potential risk for adverse reactions. A dose adjustment to the next dose level can be made after 4 weeks, if necessary. When titrating to the maximum dose of 40mg, specialist supervision is recommended and should only be considered in patients with severe hypercholesterolaemia at high cardiovascular risk. Doses may be given at any time of the day with or without food. *Elderly*: A start dose of 5mg is recommended in patients >70 years. *Asian patients*: 5mg recommended start dose. *Renal impairment*: 5mg recommended start dose in patients with moderate renal impairment (creatinine clearance <60 ml/min). *Patients with predisposing factors to myopathy*: 5mg recommended start dose (refer to SmPC). *Children*: Safety and efficacy have not been established in children.

Contraindications Hypersensitivity to any of the ingredients; active liver disease or unexplained persistent elevations in serum transaminases; severe renal impairment; myopathy; concomitant ciclosporin; pregnancy and breast-feeding; women of child-bearing potential not using contraception. In addition, CRESTOR 40mg is contraindicated with concomitant fibrates, in patients with predisposing factors for developing myopathy/rhabdomyolysis and patients of Asian origin (refer to SmPC).

Precautions *Renal effects*: Proteinuria seen in patients treated with higher doses of CRESTOR, in particular 40 mg, where it was usually transient or intermittent. A causal relationship has not been identified between proteinuria and acute or progressive renal disease. An assessment of renal function should be considered during routine follow-up of patients treated with CRESTOR 40 mg. *Muscle effects*: Patients with signs and symptoms of myopathy should have their creatine kinase (CK) levels monitored. CRESTOR should be discontinued if CK levels are markedly elevated or, if muscle symptoms are severe and cause daily discomfort. Risk of myositis and myopathy may increase when administered with certain other drugs, combination of CRESTOR with gemfibrozil is not recommended and other fibrates should be used with caution with CRESTOR 5, 10 and 20mg. As with other HMG-CoA reductase inhibitors CRESTOR should be prescribed with caution in patients with predisposing factors for myopathy and rhabdomyolysis (refer to SmPC). CRESTOR should not be used in patients with an acute, serious condition suggestive of myopathy or predisposing to the development of renal failure secondary to rhabdomyolysis. Rarely, rhabdomyolysis, occasionally associated with impairment of renal function, has been reported with all doses and in particular with doses >20mg. *Liver effects*: CRESTOR should be used with caution in patients with a history of liver disease and/or alcoholism. Liver function tests should be carried out, prior to, and 3 months following the initiation of treatment. CRESTOR should be discontinued or the dose reduced if the level of serum transaminases is greater than 3-times the upper limit of normal. *Race*: Increased systemic exposure has been seen in Asian subjects. CRESTOR 40mg is contraindicated and caution should be used when making other dose decisions in such patients. *Pregnancy and lactation*: CRESTOR is contraindicated in pregnancy and lactation. *Drug interactions*: CRESTOR is neither an inhibitor nor inducer of cytochrome P450 isoenzymes. CRESTOR may potentiate the anticoagulant effect of Vitamin K antagonists, monitor International Normalised Ratio (INR) upon initiation, dose adjustment

and discontinuation of CRESTOR therapy. Caution should be exercised with concomitant use of CRESTOR and ezetimibe. Decrease in CRESTOR levels seen when co-administered with erythromycin or antacids containing aluminium and magnesium hydroxide. Increase in oral contraceptive level seen when co-administered with CRESTOR. Concomitant use of CRESTOR with protease inhibitors is not recommended.

Undesirable events: Side effects most frequently reported in controlled clinical studies: headache, dizziness, constipation, nausea, abdominal pain, myalgia, asthenia. Uncommon: pruritus, rash and urticaria. Rarely: arthralgia, myopathy (including myositis), rhabdomyolysis, hypersensitivity reactions including angioedema, pancreatitis. Very rarely: jaundice, hepatitis, polyneuropathy, haematuria, memory loss. Other usually transient side effects: elevations in transaminases and CK levels, proteinuria (refer to SmPC).

Legal Category POM

Marketing authorisation numbers CRESTOR 5mg PL 17901/0243; CRESTOR 10mg PL 17901/0201; CRESTOR 20mg PL 17901/0202; CRESTOR 40mg PL 17901/0203

Basic NHS price CRESTOR 5mg (28 tablets), £18.03; CRESTOR 10mg (28 tablets), £18.03; CRESTOR 20mg (28 tablets), £26.02; CRESTOR 40mg (28 tablets) £29.69

Further information is available from the Marketing Authorisation Holder AstraZeneca UK Ltd, 600 Capability Green, Luton, LU1 3LU, UK.

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Editing Notes:

1. “Refer to Summary of Product Characteristics before prescribing” should be printed in bold.
2. Type should be such that a lower case letter “x” is no less than 1mm in height.
3. Lines should be no more than 100 characters in length, including spaces.
4. Sufficient space should be allowed between lines to facilitate easy reading.
6. A clear style of type should be used.
7. There should be adequate contrast between the colour of the text and the background.
8. Dark print on a light background is preferable.
9. Emboldening headings and starting each section on a new line aids legibility.