

הודעה על החמרה (מידע בטיחות) בעלון לרופא
(מעודכן 3102.50)

תאריך דצמבר 2013

Crestor 5 mg , Crestor 10mg, Crestor 20mg, Crestor 40mg **שם תכשיר באנגלית ומספר הרישום**

מס' רישום
 Crestor 5 mg: 139 22 31615 00
 Crestor 10 mg: 129 74 30798 00
 Crestor 20 mg: 129 75 30799 00
 Crestor 40 mg: 129 76 30800 00

שם בעל הרישום אסטרהזניקה (ישראל) בע"מ

טופס זה מיועד לפרוט החמרות בלבד !

עלון לרופא:

ההחמרות המבוקשות

טקסט חדש	טקסט נוכחי	פרק בעלון
<p>In the JUPITER study, the reported overall frequency of diabetes mellitus was 2.8% in rosuvastatin and 2.3% in placebo, mostly in patient with fasting glucose 5.6 to 6.9 mmol/l.</p> <p>Endocrine Effects</p> <p>Although clinical studies have shown that CRESTOR alone does not reduce basal plasma cortisol concentration or impair adrenal reserve, caution should be exercised if CRESTOR is administered concomitantly with drugs that may decrease the levels or activity of endogenous steroid hormones such as ketoconazole, spironolactone, and cimetidine.</p>		<p>Special Warnings and Special Precautions for Use</p>
<p>Fusidic Acid: Interaction studies with rosuvastatin and fusidic acid have not been conducted. As with other statins, muscle related events, including rhabdomyolysis, have been reported in post-marketing experience with rosuvastatin and fusidic acid given concurrently. Patients should be closely monitored and temporary suspension of rosuvastatin treatment may be appropriate.</p>		<p>Interaction with Other Medicaments and Other Forms of Interaction</p>

Colchicine: Cases of myopathy, including rhabdomyolysis, have been reported with HMG-CoA reductase inhibitors, including rosuvastatin, coadministered with colchicine, and caution should be exercised when prescribing CRESTOR with colchicine.

Table 1 Effect of co-administered medicinal products on rosuvastatin exposure (AUC; in order of decreasing magnitude) from published clinical trials

Interacting drug dose regimen	Rosuvastatin dose regimen	Change in rosuvastatin AUC
Clopidogrel 300 mg loading, followed by 75 mg at 24 hours	20 mg, single dose	2-fold

Change to table according to UK PI May 2013

- Frequency per US PI
- Memory loss
- Forgetfulness
- Amnesia
- Memory impairment

frequency unknown: peripheral neuropathy

Other effects:

In a long-term controlled clinical trial CRESTOR was shown to have no harmful effects on the ocular lens.
In CRESTOR treated patients, there was no impairment of adrenocortical function.

4.8 Undesirable effects

עלון לצרכן

ההחמרות המבוקשות		
טקסט חדש	טקסט נוכחי	פרק בעלון
• הינך סובל מרמות גבוהות של סוכר בדם או HbA1c גבוהה		אזהרות מיוחדות הנוגעות בשימוש בקרטור תופעות לוואי
• חוסר תחושה, עקצוץ או כאב בזרועות או ברגליים (ניורופתיה היקפית)		