Summary of investigation results
Rosuvastatin calcium

June 3, 2014

Non-proprietary Name
Rosuvastatin calcium

Brand Name (Marketing Authorization Holder)
CRESTOR tablets 2.5 mg, 5 mg (AstraZeneca K.K.)

Indications
Hypercholesterolaemia and familial hypercholesterolemia

Summary of revision
- ‘Erythema multiforme’ should be added in Clinically significant adverse reactions section.
- ‘Peripheral nerve disorder’ should be added in Clinically significant adverse reactions section.

Background of the revision and investigation results
- Erythema multiforme
  Cases of erythema multiforme have been reported in patients treated with rosuvastatin calcium in Japan. The MHLW/PMDA concluded that revision of the package insert was necessary.
- Peripheral nerve disorder
  Cases of Peripheral nerve disorder have been reported in patients treated with rosuvastatin calcium in foreign countries and a company core data sheet (CCDS)* has been updated.

Following an investigation result based on opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.
The number of reported adverse reaction and fatal cases in the last 3 fiscal years

- A total of 4 erythema multiforme cases has been reported (including 2 cases in which causality could not be ruled out). Of the 4 cases, no fatal cases have been reported.
- A peripheral nerve disorder case, in which no causality was found, has been reported. No fatal case has been reported.

NOTE

*CCDS is prepared by a marketing authorization holder and covers material relating to safety, indications, dosing, pharmacology, and other information concerning the product.