This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

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.

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

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.

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