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

Loratadine

July 8, 2014

Non-proprietary Name

Loratadine

Brand Name (Marketing Authorization Holder)

CLARITIN tablets 10 mg, CLARITIN REDITABS tablets 10 mg, CLARITIN dry syrup 1% (MSD K.K.) and the others

Indications

Allergic rhinitis, urticaria, and cutaneous diseases (eczema/dermatitis and cutaneous pruritus) with pruritus

Summary of revision

'Convulsion' should be added in Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of convulsion have been reported in patients treated with loratadine in foreign countries and a company core datasheet (CCDS)* has been updated. Further, cases of convulsion have been reported also in Japan. 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 in Japan

A total of 4 convulsion-associated cases has been reported (including 2 cases in which causality could not be ruled out). Of the 4 cases, no fatalies have 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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