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

Summary of investigation results Fexofenadine hydrochloride/Pseudoephedrine hydrochloride

April 21, 2016

Non-proprietary name

Fexofenadine hydrochloride/Pseudoephedrine hydrochloride

Brand name (Marketing authorization holder)

Dellegra Combination Tablets (Sanofi K.K.)

Indications

Allergic rhinitis

Summary of revision

“Acute generalised exanthematous pustulosis” should be newly added in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of acute generalised exanthematous pustulosis in which a causal relationship to the product could not be ruled out have been reported in patients treated with pseudoephedrine hydrochloride both overseas and in Japan. In addition, the company core datasheet (CCDS)* has been updated. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A case of acute generalised exanthematous pustulosis has been reported (a causal

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relationship to the product could not be ruled out for this patient). No fatality has been reported.

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

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