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*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.*

# Revision of Precautions Fexofenadine hydrochloride/ Pseudoephedrine hydrochloride

April 21, 2016

## **Non-proprietary name**

Fexofenadine hydrochloride/Pseudoephedrine hydrochloride

## **Safety measure**

Precautions should be revised in the package insert.

In the Clinically significant adverse reaction subsection of the Adverse reaction section, the following text should be added (underlined parts are revised):

Acute generalised exanthematous pustulosis:

Acute generalised exanthematous pustulosis may occur. Patients should be carefully monitored. If symptoms, such as pyrexia, erythema, and many small pustules, are observed, administration of this drug should be discontinued, and appropriate measures should be adopted.