



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

Ibuprofen/Pseudoephedrine hydrochloride/Chlorpheniramine maleate/Dihydrocodeine phosphate/Caffeine Anhydrous (OTC drugs) and Ibuprofen/Pseudoephedrine hydrochloride/L-Carbocisteine/*d*-Chlorpheniramine maleate/Dihydrocodeine phosphate/Caffeine anhydrous (OTC drugs)

July 8, 2014

Non-proprietary Name

- a. Ibuprofen/Pseudoephedrine hydrochloride/Chlorpheniramine maleate/Dihydrocodeine phosphate/Caffeine Anhydrous (OTC drugs)
- b. Ibuprofen/Pseudoephedrine hydrochloride/L-Carbocisteine/*d*-Chlorpheniramine maleate/Dihydrocodeine phosphate/Caffeine anhydrous (OTC drugs)

Safety measure

Precautions should be revised in the package inserts.

In Consultation section, the following texts should be added (underlined parts are revised):

The following symptoms may be adverse reactions, therefore if the following symptoms are observed after administration of this drug, immediately discontinue this drug and contact a physician, pharmacist, or registered salesperson for a consultation with this package insert.

The following serious symptoms occur infrequently. Immediately seek medical aid if you experience any of these signs and symptoms.

Oculomucocutaneous syndrome (Stevens-Johnson syndrome), toxic epidermal necrolysis, acute generalised exanthematous pustulosis:

Hyperthermia, ocular hyperaemia, eye discharge, lip erosion, pain throat, widespread skin rash/redness, small pimples (small pustules) on reddened skin, general malaise, anorexia, etc. may persist or suddenly worsen.