



Summary of investigation results

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)

Brand Name (Marketing Authorization Holder)

- a. Benza Block L, Benza Block L tablets (Takeda Pharmaceutical Company Limited)
- b. Benza Block L Plus, Benza Block L Plus tablets (Takeda Pharmaceutical Company Limited)

Indications

- a. Alleviation of cold symptoms (sore throat, fever, nasal congestion, nasal mucus, chills, headache, arthralgia, myalgia, cough, and sneezing)
- b. Alleviation of cold symptoms (sore throat, fever, nasal congestion, sputum, nasal mucus, chills, headache, arthralgia, myalgia, cough, and sneezing)

Summary of revision

‘Acute generalised exanthematous pustulosis’ should be added in oculomucocutaneous syndrome and toxic epidermal necrolysis subsection of Consultation section.

Background of the revision and investigation results

Cases of acute generalised exanthematous pustulosis have been reported in patients treated with Benza Block L or Benza Block L Plus in Japan. Following an investigation result based on opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package inserts was necessary.

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

An acute generalised exanthematous pustulosis-associated case, in which causality could not be ruled out, has been reported. No fatality has been reported.