



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

Dihydrocodeine phosphate/platycodon fluidextract/glycyrrhiza extract/plantago herb extract/peony root extract (prescription drugs)

**Dihydrocodeine phosphate/dl-methylephedrine hydrochloride/
chlorpheniramine maleate (prescription drugs)**

**Dihydrocodeine phosphate/
diprophylline/dl-methylephedrine hydrochloride/
diphenhydramine salicylate/acetaminophen/bromovalerylurea
(prescription drugs)**

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

Dihydrocodeine phosphate/ephedrine hydrochloride/ ammonium chloride (prescription drugs)

July 9, 2019

Therapeutic category

Antitussives

Antitussives and expectorants

Non-proprietary name

Dihydrocodeine phosphate/platycodon fluidextract/glycyrrhiza extract/plantago herb extract/peony root extract

Dihydrocodeine phosphate/dl-methylephedrine hydrochloride/chlorpheniramine maleate

Dihydrocodeine phosphate/diprophylline/dl-methylephedrine hydrochloride/diphenhydramine salicylate/acetaminophen/bromovalerylurea

Dihydrocodeine phosphate/ephedrine hydrochloride/ammonium chloride

Safety measure

Precautions should be revised in the package insert.

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions):

Revised language is underlined.

Current	Revision
Contraindications (N/A) Important Precautions <u>This drug should not be used in children younger than 12 years old because serious respiratory depression may occur.</u>	Contraindications <u>Children younger than 12 years old</u> Important Precautions (deleted)

N/A: Not Applicable, because the section is not included in the current package insert.

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