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Pharmaceuticals and Medical Devices Agency



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

Products containing codeine phosphate hydrate (OTC drugs)

Products containing dihydrocodeine phosphate (OTC drugs)

July 9, 2019

Therapeutic category

Cold medicine, antitussives and expectorants

Non-proprietary name

Products containing codeine phosphate hydrate

Products containing dihydrocodeine phosphate

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
<p>When not to use the product</p> <p>This product should not be used in the following persons: (N/A)</p> <p>Precaution concerning Dosage and Administration</p> <p><u>For children younger than 12 years old, examination by a physician should always precede administration of this drug.</u></p>	<p>When not to use the product</p> <p>This product should not be used in the following persons: <u>Children younger than 12 years old</u> ^{note1}</p> <p>Precaution concerning Dosage and Administration (deleted)</p>

Note 1 : In the When not to use the product section, on an outer container, or a wrapper of the product, any minimum ages of 13 years or older as approved in the current dosage and administration should replace the “younger than 12 years old” in this revision.

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

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