



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

Diprophylline/Dihydrocodeine phosphate/ dl-Methylephedrine hydrochloride/ Diphenhydramine salicylate/ Acetaminophen/Bromovalerylurea

July 4, 2017

Non-proprietary name

Diprophylline/Dihydrocodeine phosphate/dl-Methylephedrine hydrochloride/
Diphenhydramine salicylate/Acetaminophen/Bromovelerylurea

Safety measure

Precautions should be revised in the package insert.

In the Careful Administration section regarding pediatric use, the following text should be revised (underlined parts are revised):

Children 12 years old and older (See Pediatric Use)

In the Important Precautions section regarding the use of this drug, the following text should be revised (underlined parts are revised):

If patients do not adequately respond to this drug even when used properly according to the dosage and administration, this drug may not be appropriate. Administration should be discontinued. When administering to children 12 years old and older, patients should be instructed for proper use and be carefully followed up.



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.

The following text should be added (underlined parts are revised):

This drug should not be used in children younger than 12 years old because serious respiratory depression may occur (see Pediatric Use).

This drug should not be used in patients younger than 18 years old who are obese or have obstructive sleep apnoea syndrome or serious lung disease because the risk of serious respiratory depression may increase.

In the Pediatric Use section, the following text should be revised (underlined parts are revised):

Children 12 years old and older should be monitored carefully particularly for adverse reactions. Careful administration is required such as limiting to the minimum dose required. (They are highly susceptible to respiratory depression. Safety in children has not been established.)

The following text should be added (underlined parts are revised):

This drug should not be used in children younger than 12 years old (They are highly susceptible to respiratory depression. Overseas there have been reports that the risk of serious respiratory depression, including death, is high in children younger than 12 years old).

* This drug is designated as a drug requiring preparation of a Drug Guide for Patients.