



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

Codeine phosphate hydrate, Dihydrocodeine phosphate

July 4, 2017

Non-proprietary name

Codeine phosphate hydrate, dihydrocodeine phosphate

Safety measure

Precautions should be revised in the package insert.

In the Careful Administration section, the following text should be deleted:

Newborns and infants (see Pediatric Use)

In the Important Precautions section, 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 for pain relief after tonsillectomy or adenoidectomy because the risk of serious respiratory depression may increase.

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



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In the Pediatric Use section, the following text should be revised (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.