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*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 and products containing dihydrocodeine phosphate (OTC drugs)

### (preparations with the administration for patients younger than 2 years old)

July 4, 2017

#### **Non-proprietary name**

Products containing codeine phosphate hydrate and products containing dihydrocodeine phosphate (OTC drugs) (preparations with the administration for patients younger than 2 years old)

#### **Safety measure**

Precautions should be revised in the package insert.

In the Consultation section, the following text should be added (underlined parts are revised):

The following persons should contact a physician, pharmacist, or registered salesperson for a consultation before administration.

Persons diagnosed as follows:

Respiratory functional disorder, obstructive sleep apnoea syndrome, obesity



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If the following symptoms are observed after taking this drug, these may be adverse reactions, so immediately discontinue the use of this drug, and show this document to your physician, pharmacist, or registered salesperson for a consultation.

The following serious symptoms occur in rare cases. In such a case, immediately seek medical aid.

Respiratory depression:

Symptoms such as shortness of breath and difficulty in breathing may occur.

In the Precautions of Dosage and Administration section, the following text

For infants younger than 2 years old, examination by a physician should always precede administration of this drug. This drug should be administered only if it is absolutely necessary.

should be revised as follows (underlined parts are revised):

For children younger than 12 years old, examination by a physician should always precede administration of this drug.

(Note) The text on an outer container or a wrapper of the product should be revised to "For children younger than 12 years old, examination by a physician should always precede administration of this drug."

(Note) Any maximum ages under 11 years old as approved in the dosage and administration should replace the "12 years old" in the Dosage and Administration section, on an outer container, or a wrapper of the product.