



Revision of Precautions

Products containing codeine phosphate hydrate and products containing dihydrocodeine phosphate (OTC drugs)

(preparations without the administration for patients younger than 12 years old)

July 4, 2017

Non-proprietary name

Products containing codeine phosphate hydrate and products containing dihydrocodeine phosphate (OTC drugs) (preparations without the administration for patients younger than 12 years old)

Safety measure

Precautions should be revised in the package insert.

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

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

Pharmaceuticals and Medical Devices Agency

Office of Safety I

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan

E-mail: safety.info@pmda.go.jp



Persons diagnosed as follows:

Respiratory functional disorder, obstructive sleep apnea syndrome, obesity

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.