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Revision of PRECAUTIONS

Diprophylline/dihydrocodeine phosphate/dl-methylephedrine hydrochloride/diphenhydramine salicylate/ acetaminophen/bromovalerylurea

October 12, 2023

Therapeutic category

Antitussives

Non-proprietary name

Diprophylline/dihydrocodeine phosphate/dl-methylephedrine hydrochloride/diphenhydramine salicylate/acetaminophen/bromovalerylurea

Safety measure

PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

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Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, PSEHB Notification No. 0611-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions):

Revised language is underlined.

Current	Revision
2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) Patients with aspirin asthma (induction of asthmatic attack due to nonsteroidal anti-inflammatory drug, etc.) or a history of the disease [It is considered that the inhibitory activity of prostaglandin synthesis is involved in the onset of aspirin asthma.]	2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) (deleted)
Patients with peptic ulcer [Symptoms may be exacerbated.]	(deleted)
Patients with serious renal disorder	(deleted)
Patients with serious blood abnormalities [Serious outcomes may occur.]	(deleted)
Patients with serious cardiac function failure [The balance of the cardiovascular system may be compromised, and cardiac failure may be aggravated.]	(deleted)
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS

9.1 Patients with Complication or History of Diseases, etc. Patients with abnormal cardiac function Symptoms may be exacerbated.	9.1 Patients with Complication or History of Diseases, etc. Patients with abnormal cardiac function Symptoms may be exacerbated or cardiac failure may be aggravated.
Patients with a history of peptic ulcer Recurrence of peptic ulcer may be promoted.	Patients with peptic ulcer or a history of the disease Symptoms may be exacerbated or recurrence may be promoted.
Patients with blood abnormalities or a history of the disease Blood disorder may occur.	Patients with blood abnormalities or a history of the disease Symptoms may be exacerbated or recurrence may be promoted.
(N/A)	Patients with aspirin asthma (induction of asthmatic attack due to nonsteroidal anti-inflammatory drug) or a history of the disease It is considered that the inhibitory activity of prostaglandin synthesis is involved in the onset of aspirin asthma, and the symptoms may be exacerbated or recurrence may be promoted.
9.2 Patients with renal impairment Patients with serious renal impairment This drug should not be administered. Serious outcomes may occur.	9.2 Patients with renal impairment (deleted)
Patient with renal impairment or a history of the disease (excluding those with serious renal impairment)	Patients with renal impairment or a history of the disease Dose reduction and prolongation of dosing intervals should be

Renal function may worsen.	considered. Symptoms may be exacerbated or recurrence may be promoted.

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.