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.
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.

<table>
<thead>
<tr>
<th>Current</th>
<th>Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2. CONTRAINDICATIONS</strong> (This drug is contraindicated to the following patients.)</td>
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<tr>
<td>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.]</td>
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<td>Patients with peptic ulcer [Symptoms may be exacerbated.]</td>
<td>(deleted)</td>
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<tr>
<td>Patients with serious renal disorder</td>
<td>(deleted)</td>
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<tr>
<td>Patients with serious blood abnormalities [Serious outcomes may occur.]</td>
<td>(deleted)</td>
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<tr>
<td>Patients with serious cardiac function failure [The balance of the cardiovascular system may be compromised, and cardiac failure may be aggravated.]</td>
<td>(deleted)</td>
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</tbody>
</table>

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS

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9.1 Patients with Complication or History of Diseases, etc.

- **Patients with abnormal cardiac function**
  - Symptoms may be exacerbated.

- **Patients with a history of peptic ulcer**
  - Recurrence of peptic ulcer may be promoted.

- **Patients with blood abnormalities or a history of the disease**
  - Blood disorder may occur.

(N/A)

9.2 Patients with renal impairment

- **Patients with serious renal impairment**
  - This drug should not be administered. Serious outcomes may occur.

- **Patient with renal impairment or a history of the disease (excluding those with serious renal impairment)**
  - 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.