Revision of PRECAUTIONS

Acetaminophen (suppository)

October 12, 2023

Therapeutic category
Antipyretics, analgesics and anti-inflammatory agents

Non-proprietary name
Acetaminophen (suppository)

Safety measure
PRECAUTIONS should be revised.
## Contraindications
This drug is contraindicated to the following patients:

- Patients with serious blood abnormalities. *Serious outcomes may occur.*
- Patients with serious renal disorder. *Serious outcomes may occur.*
- Patients with serious cardiac function failure. *The balance of the cardiovascular system may be compromised, and cardiac failure may be aggravated.*
- 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.*

## Precautions for Dosage and Administration

The maximum dose for patients with aspirin asthma or a history of the disease should be 300 mg or less of acetaminophen per dose.

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**Current** | **Revision**
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Contraindications (This drug is contraindicated to the following patients.) | Contraindications (This drug is contraindicated to the following patients.)
Patients with serious blood abnormalities [Serious outcomes may occur.] | (deleted)
Patients with serious renal disorder [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)
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.] | (deleted)
Precautions for Dosage and Administration | Precautions for Dosage and Administration
(N/A) | The maximum dose for patients with aspirin asthma or a history of the disease should be 300 mg or less of acetaminophen per dose.
Careful Administration (Careful administration of this drug is required) | Careful Administration (Careful administration of this drug is required)
in the following patients.)
Patients with blood abnormalities or a history of the disease [Blood disorder may occur.]

Patients with renal disorder or a history of the disease [Renal function may worsen.]

Patients with abnormal cardiac function [Symptoms may be exacerbated.]

(N/A)

in the following patients.)
Patients with blood abnormalities or a history of the disease [Symptoms may be exacerbated or recurrence may be promoted.]

Patients with renal disorder or a history of the disease [Dose reduction and prolongation of dosing intervals should be considered. Symptoms may be exacerbated or recurrence may be promoted.]

Patients with abnormal cardiac function [Symptoms may be exacerbated or cardiac failure may be aggravated.]

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.]

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

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.
| Patients with serious blood abnormalities [Serious outcomes may occur.] | following patients.) |
| Patients with serious renal disorder | (deleted) |
| Patients with serious cardiac function failure [The balance of the cardiovascular system may be compromised, and cardiac failure may be aggravated.] | (deleted) |
| 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.] | (deleted) |

| 7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION | 7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION |
| (N/A) | The maximum dose for patients with aspirin asthma or a history of the disease should be 300 mg or less of acetaminophen per dose. |

<p>| 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS | 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS |
| 9.1 Patients with Complication or History of Diseases, etc. | 9.1 Patients with Complication or History of Diseases, etc. |
| Patients with blood abnormalities or a history of the disease | Patients with blood abnormalities or a history of the disease |</p>
<table>
<thead>
<tr>
<th>Conditions</th>
<th>Potential Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excluding those with serious blood abnormalities</td>
<td>Blood disorder may occur.</td>
</tr>
<tr>
<td>Patients with abnormal cardiac function</td>
<td>Symptoms may be exacerbated.</td>
</tr>
<tr>
<td>Patients with bronchial asthma</td>
<td>Symptoms may be exacerbated.</td>
</tr>
<tr>
<td>Patients with aspirin asthma or a history of the disease</td>
<td>Symptoms may be exacerbated or recurrence may be promoted.</td>
</tr>
<tr>
<td>Renal disorder or a history of the disease</td>
<td>Symptoms may be exacerbated or cardiac failure may be aggravated.</td>
</tr>
</tbody>
</table>

**9.2 Patients with renal impairment**

- Patients with serious renal disorder
  - This drug should not be administered. Serious outcomes may occur.
- Patients with renal disorder or a history of the disease (excluding those with serious renal disorder)
  - Dose reduction and prolongation of dosing intervals should be...
Renal function may worsen. Symptoms may be exacerbated or recurrence may be considered. Symptoms may be exacerbated or recurrence may be promoted.

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