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Translated by  
Pharmaceuticals and Medical Devices Agency



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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

## Acetaminophen (injections)

October 12, 2023

### **Therapeutic category**

Antipyretics, analgesics and anti-inflammatory agents

### **Non-proprietary name**

Acetaminophen (injections)

### **Safety measure**

PRECAUTIONS should be revised.

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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
<p>2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)</p> <p><u>Patients with peptic ulcer [Symptoms may be exacerbated.]</u></p> <p><u>Patients with serious blood abnormalities [Serious outcomes may occur.]</u></p> <p><u>Patients with serious renal disorder</u></p> <p><u>Patients with serious cardiac function failure [The balance of the cardiovascular system may be compromised, and cardiac failure may be aggravated.]</u></p> <p><u>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.]</u></p>	<p>2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)</p> <p>(deleted)</p> <p>(deleted)</p> <p>(deleted)</p> <p>(deleted)</p> <p>(deleted)</p>
<p>7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p>	<p>7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p>

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<p>(N/A)</p> <p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.1 Patients with Complication or History of Diseases, etc.</p> <p>Patients with <u>a history of peptic ulcer</u> Recurrence <u>of peptic ulcer</u> may be promoted.</p> <p>Patients with blood abnormalities or a history of the disease <u>(excluding those with serious blood abnormalities)</u> <u>Blood disorder</u> may <u>occur</u>.</p> <p>Patients with abnormal cardiac function <u>(excluding those with serious cardiac function failure)</u> Symptoms may be exacerbated.</p> <p>Patients with bronchial asthma <u>(excluding those with aspirin asthma or a history of the disease)</u> Symptoms may be exacerbated.</p> <p>(N/A)</p>	<p><u>The maximum dose for patients with aspirin asthma or a history of the disease should be 300 mg or less of acetaminophen per dose.</u></p> <p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.1 Patients with Complication or History of Diseases, etc.</p> <p>Patients with peptic ulcer <u>or a history of the disease</u> <u>Symptoms may be exacerbated or</u> recurrence may be promoted.</p> <p>Patients with blood abnormalities or a history of the disease <u>Symptoms</u> may <u>be exacerbated or recurrence may be promoted.</u></p> <p>Patients with abnormal cardiac function Symptoms may be exacerbated <u>or cardiac failure may be aggravated.</u></p> <p>Patients with bronchial asthma Symptoms may be exacerbated.</p> <p><u>Patients with aspirin asthma (induction of asthmatic attack due to nonsteroidal anti-inflammatory drug) or a history of the disease</u> <u>It is considered that the inhibitory activity of prostaglandin synthesis</u></p>
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<p>9.2 Patients with renal impairment</p> <p><u>Patients with serious renal disorder</u></p> <p><u>This drug should not be administered. Serious outcomes may occur.</u></p> <p>Patients with renal disorder or a history of the disease <u>(excluding those with serious renal disorder)</u></p> <p><u>Renal function may worsen.</u></p>	<p><u>is involved in the onset of aspirin asthma, and the symptoms may be exacerbated or recurrence may be promoted.</u></p> <p>9.2 Patients with renal impairment</p> <p><u>(deleted)</u></p> <p>Patients with renal disorder or a history of the disease</p> <p><u>Dose reduction and prolongation of dosing intervals should be considered. Symptoms may be exacerbated or recurrence may be promoted.</u></p>
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N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.

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