

Published by  
Ministry of Health, Labour and Welfare



Translated by  
Pharmaceuticals and Medical Devices Agency



---

*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 (suppository)

October 12, 2023

### **Therapeutic category**

Antipyretics, analgesics and anti-inflammatory agents

### **Non-proprietary name**

Acetaminophen (suppository)

### **Safety measure**

PRECAUTIONS should be revised.

**Pharmaceuticals and Medical Devices Agency**

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan  
E-mail: [safety.info@pmda.go.jp](mailto:safety.info@pmda.go.jp)

Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director-General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
<p>Contraindications (This drug is contraindicated to the following patients.)</p> <p><u>Patients with serious blood abnormalities [Serious outcomes may occur.]</u></p> <p><u>Patients with serious renal disorder [Serious outcomes may occur.]</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>Contraindications (This drug is contraindicated to the following patients.)</p> <p>(deleted)</p> <p>(deleted)</p> <p>(deleted)</p> <p>(deleted)</p>
<p>Precautions for Dosage and Administration</p> <p>(N/A)</p>	<p>Precautions for Dosage and Administration</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>Careful Administration (Careful administration of this drug is required)</p>	<p>Careful Administration (Careful administration of this drug is required)</p>

**Pharmaceuticals and Medical Devices Agency**

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan  
E-mail: [safety.info@pmda.go.jp](mailto:safety.info@pmda.go.jp)

<p>in the following patients.)</p> <p>Patients with blood abnormalities or a history of the disease [<u>Blood disorder may occur.</u>]</p> <p>Patients with renal disorder or a history of the disease [<u>Renal function may worsen.</u>]</p> <p>Patients with abnormal cardiac function [Symptoms may be exacerbated.]</p> <p>(N/A)</p>	<p>in the following patients.)</p> <p>Patients with blood abnormalities or a history of the disease [<u>Symptoms may be exacerbated or recurrence may be promoted.</u>]</p> <p>Patients with renal disorder or a history of the disease [<u>Dose reduction and prolongation of dosing intervals should be considered. Symptoms may 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><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, and the symptoms may be exacerbated or recurrence may be promoted.]</u></p>
---	---

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.

Current	Revision
2. CONTRAINDICATIONS (This drug is contraindicated to the	2. CONTRAINDICATIONS (This drug is contraindicated to the

**Pharmaceuticals and Medical Devices Agency**

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan  
E-mail: [safety.info@pmda.go.jp](mailto:safety.info@pmda.go.jp)

<p>following patients.)</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>following patients.)</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>
<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. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p>
<p>9.1 Patients with Complication or History of Diseases, etc.</p>	<p>9.1 Patients with Complication or History of Diseases, etc.</p>
<p>Patients with blood abnormalities or a history of the disease</p>	<p>Patients with blood abnormalities or a history of the disease</p>

**Pharmaceuticals and Medical Devices Agency**

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan  
E-mail: [safety.info@pmda.go.jp](mailto:safety.info@pmda.go.jp)

<p><u>(excluding those with serious blood abnormalities)</u>  <u>Blood disorder may 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>9.2 Patients with renal impairment  <u>Patients with serious renal disorder</u>  <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>Symptoms may 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 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  <u>(deleted)</u></p> <p>Patients with renal disorder or a history of the disease  <u>Dose reduction and prolongation of dosing intervals should be</u></p>
--	---

**Pharmaceuticals and Medical Devices Agency**

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan  
E-mail: [safety.info@pmda.go.jp](mailto:safety.info@pmda.go.jp)

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.

**Pharmaceuticals and Medical Devices Agency**

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan  
E-mail: [safety.info@pmda.go.jp](mailto:safety.info@pmda.go.jp)