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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 (injections)

Isopropylantipyrene/acetaminophen/allylisopropylacetylurea/anhydrous caffeine

January 17, 2023

Therapeutic category

Antipyretics, analgesics and anti-inflammatory agents

Non-proprietary name

Acetaminophen

Isopropylantipyrene/acetaminophen/allylisopropylacetylurea/anhydrous caffeine

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, etc. PSEHB Notification No. 0611-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): Revised language is underlined.

Current	Revision
<p>11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)</p>	<p>11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Drug-induced hypersensitivity syndrome</u> <u>Initial symptoms of rash and pyrexia, followed by serious delayed symptoms of hypersensitivity accompanied by hepatic impairment, swollen lymph nodes, increased white blood cell, eosinophilia, and appearance of atypical lymphocytes may occur. Symptoms are often accompanied by virus reactivation, such as human herpes virus type 6 (HHV-6). Caution is required for recurrence or prolongation of rash, pyrexia, and hepatic impairment, etc. that may occur even after discontinuation of administration.</u></p>

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

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