

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

Attachment 1
August 25, 2026

【Therapeutic category】 114 Antipyretics, analgesics and anti-inflammatory agents

118 Agents used for common cold

222 Antitussives

【Non-proprietary name】 Acetaminophen

Isopropylantipyrine/acetaminophen/allylisopropylacetylurea/anhydrous caffeine

Tramadol hydrochloride/acetaminophen

Salicylamide/acetaminophen/anhydrous caffeine/chlorpheniramine maleate

Salicylamide/acetaminophen/anhydrous caffeine/promethazine methylenedisalicylate

Diprophylline/dihydrocodeine phosphate/dl-methylephedrine hydrochloride/diphenhydramine

salicylate/acetaminophen/bromovalerylurea

【Safety measure】 PRECAUTIONS should be revised.

A revised description is underlined.

Current	Revision
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS
9.1 Patients with Complications or a History of Diseases, etc.	9.1 Patients with Complications or a History of Diseases, etc.
N/A	<u>Patients with a predisposition to accumulation of pyroglutamic acid due to serious renal impairment, liver impairment (excluding serious liver impairment), sepsis, malnutrition, etc.</u>
	<u>Pyroglutamic acid excretion is inhibited or glutathione deficiency occurs in</u>

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	<u>these patients. Administration of this drug may promote accumulation of pyroglutamic acid to cause high-anion gap metabolic acidosis.</u>
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N/A: Not Applicable. No corresponding description is included in the current PRECAUTIONS.

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