

Summary of Investigation Results

Preparations containing acetaminophen (oral dosage form, suppositories, injections) (prescription drug)

Non-proprietary name	Non-proprietary name	Brand name (marketing authorization holder)
Brand name	See Attachment	See Attachment
Japanese market launch	See Attachment	
Indications	See Attachment	
Summary of revisions	"Patients with a predisposition to accumulation of pyroglutamic acid due to serious renal impairment/liver impairment (excluding serious liver impairment)/sepsis/malnutrition, etc." should be added to the 9.1 Patients with Complication or History of Diseases, etc. section in 9 PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS.	
Investigation results and background of the revision	In light of the metabolic pathway of preparations containing acetaminophen and the mechanism of the onset of adverse reactions thereto, administration to patients predisposed to accumulation of pyroglutamic acid may promote its accumulation , which may result in high anion gap metabolic acidosis. Therefore, MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.	

Attachment

No.	Non-proprietary name	Brand name	Marketing authorization holder	Japanese market launch	Indications
1	Acetaminophen (oral dosage form)	Calonal powder, Calonal tablets 200, 300, 500, Calonal Fine Gran. 20%, 50%, Calonal Syrup 2%, and the others	AYUMI Pharmaceutical Corporation, and the others	Powder: May 2010 Tablets 200: July 1996 Tablets 300: July 2003 Tablets 500: February 2015 Fine Gran. 20%: July 1984 Fine Gran. 50%: July 2003 Syrup: June 2000	< Powder, tablets, granules > ○ Analgesia in various diseases and symptoms ○ Antipyresis and analgesia for the following diseases: Acute upper respiratory inflammation (including acute upper respiratory inflammation associated with acute bronchitis) ○ Antipyresis and analgesia in the field of pediatrics < Syrup > Antipyresis and analgesia in the field of pediatrics
2	Acetaminophen (suppositories)	(1) Alpin Suppositories 50, 100, 200, and the others (2) Anhiba pediatric suppository 50 mg, 100 mg, 200 mg, and the others (3) Calonal Supp. 50 for Pediatric, Calonal Supp. 100, 200, 400, and the others	(1) Hisamitsu Pharmaceutical Co., Inc., and the others (2) Viatrix Pharmaceuticals Japan G.K. , and the others (3) AYUMI Pharmaceutical Corporation, and the others	(1) 50 mg: July 1984 (1) 100 mg: February 1980 (1) 200 mg: July 1984 (2) 50 mg: July 1994 (2) 100 mg: February 1980 (2) 200 mg: September 1981 (3) 50 mg: January 2010 (3) 100 mg, 200 mg: October 1987 (3) 400 mg: July 2015	Antipyresis and analgesia in the field of pediatrics
3	Acetaminophen (injections)	acelio Bag for Intravenous Injection 1000 mg	Terumo Corporation	February 2017	Pain and pyrexia when administration of oral preparations and suppositories is difficult
4	Pyrazolone-based antipyretics, analgesics and antiinflammatory	SG Combination Granules	Shionogi Pharma Co., Ltd.	July 2003	Antipyresis for common cold, ear pain, sore throat, painful menses, headache, toothache, symptomatic

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	combination drug (4)				neuralgia, traumatic pain
5	Tramadol hydrochloride/ acetaminophen	Tramcet Combination Tablets, and the others	Janssen Pharmaceutical K.K., and the others	July 2011	Analgesia for the following diseases that cannot be managed by treatment with non-opioid analgesics: ○ Non-cancerous chronic pain ○ Pain after tooth extraction
6	Diprophylline/ dihydrocodeine phosphate/dl- methylephedrine hydrochloride/ diphenhydramine salicylate/acetamin ophen/ bromovalerylurea	Coughcode-N Combination Tablets	Viatis Healthcare G.K.	August 2002	Antitussive, pain relief, and antipyresis in common cold syndrome Antitussive in bronchitis
7	Non-pyrine common cold medicine (2)	Pelex combination granule	TAIHO Pharmaceutical Co., Ltd.	September 1967	Improvement and alleviation in the following symptoms accompanying common cold or upper respiratory inflammation: Nasal discharge, nasal congestion, pharyngeal/laryngeal pain, cough, sputum, headache, arthralgia, myalgia, pyrexia
8	Non-pyrine common cold medicine (3)	Pediatric Pelex combination granule	TAIHO Pharmaceutical Co., Ltd.	August 1972	Improvement and alleviation in the following symptoms accompanying common cold or upper respiratory inflammation: Nasal discharge, nasal congestion, pharyngeal/laryngeal pain, cough, sputum, headache, arthralgia, myalgia, pyrexia
9	Non-pyrine common cold medicine (4)	PL Combination Granules, and the others	Shionogi Pharma Co., Ltd., and the others	February 1962	Improvement and alleviation in the following symptoms accompanying common cold

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					or upper respiratory inflammation: Nasal discharge, nasal congestion, pharyngeal/laryngeal pain, headache, arthralgia, myalgia, pyrexia
10	Non-pyrine common cold medicine (5)	PL Combination Granules for Infants	Shionogi Pharma Co., Ltd.	April 1962	Improvement and alleviation in the following symptoms accompanying common cold or upper respiratory inflammation: Nasal discharge, nasal congestion, pharyngeal/laryngeal pain, headache, arthralgia, myalgia, pyrexia