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Summary of Investigation Results

Aspirin Aspirin/dialuminate Aspirin/vonoprazan fumarate Aspirin/lansoprazole Clopidogrel sulfate/aspirin

January 13, 2026

Non-proprietary name

- a. Aspirin (preparations indicated for prevention of thrombus and embolus formation)
- b. Aspirin/dialuminate
- c. Aspirin/vonoprazan fumarate
- d. Aspirin/lansoprazole
- e. Clopidogrel sulfate/aspirin
- f. Aspirin (preparations indicated for antipyresis/analgesia/anti-inflammation)

Brand name (marketing authorization holder)

See attachment.

Japanese market launch

See attachment.

Indications

See attachment.

Summary of revisions

"Acute coronary syndrome accompanying allergic reaction" should be added to the Clinically Significant Adverse Reactions section.

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Investigation results and background of the revision

Cases involving acute coronary syndrome accompanying allergic reaction were evaluated. Cases in which a causal relationship between preparations containing aspirin and acute coronary syndrome accompanying allergic reaction was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

Reference: Number of cases and patient mortalities involving acute coronary syndrome accompanying allergic reaction (Kounis syndrome) reported in Japan^{*1} and overseas^{*2}

a. and f.

A total of 6 cases have been reported in Japan to date (including 1 case in which a causal relationship between the drug and the event was reasonably possible.)

No patient mortalities have been reported in Japan to date.

b. to e.

No cases have been reported in Japan to date.

a. and f.

A total of 18 cases have been reported overseas to date (including 7 cases in which a causal relationship between the drug and the event was reasonably possible).

One instance of patient mortality has been reported overseas to date (A causal relationship between the drug and the death following the event could not be established for this case).

b. to e.

No cases have been reported overseas to date.

*1: Among cases collected in the PMDA's safety database for drugs, cases which correspond to MedDRA version 28.0 PT "Kounis syndrome" were retrieved.

*2: Cases provided by the marketing authorization holder as cases suspected of acute coronary syndrome (Kounis syndrome) accompanying allergic reaction due to drug



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administration.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the "Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency" (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

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Attachment

	Non-proprietary name	Brand name	Marketing authorization holder	Japanese market launch	Indications
a.	Aspirin (preparations indicated for prevention of thrombus and embolus formation)	Bayaspirin Tablets 100 mg, etc.	Bayer Yakuhin, Ltd. and the others	January 2001	<ul style="list-style-type: none">○ Prevention of thrombus and embolus formation in the following diseases:<ul style="list-style-type: none">• Angina pectoris (chronic stable angina, unstable angina)• Myocardial infarction• Ischemic cerebrovascular disorder (transient ischaemic attack (TIA), cerebral infarction)○ Prevention of thrombus/embolus formation after coronary artery bypass grafting (CABG) or percutaneous transluminal coronary angioplasty (PTCA)○ Kawasaki disease (including cardiovascular sequelae of Kawasaki disease)
b.	Aspirin/dialuminate	Bufferin Combination Tablets A81, etc.	Lion Corporation and the others	November 2000*	<ul style="list-style-type: none">○ Prevention of thrombus and embolus formation in the following diseases:<ul style="list-style-type: none">Angina pectoris (chronic stable angina pectoris, unstable angina)Myocardial infarctionIschemic cerebrovascular disorder (transient ischaemic attack)

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					<p>(TIA), cerebral infarction)</p> <ul style="list-style-type: none">○ Prevention of thrombus/embolus formation after coronary artery bypass grafting (CABG) or percutaneous transluminal coronary angioplasty (PTCA)○ Kawasaki disease (including cardiovascular sequelae of Kawasaki disease)
c.	Aspirin/vonoprazan fumarate	Cabpirin Combination Tablets	Takeda Pharmaceutical Company Limited	May 2020	<p>Prevention of thrombus/embolus formation in the following diseases or after surgery (limited to patients with a history of gastric ulcer or duodenal ulcer):</p> <ul style="list-style-type: none">• Angina pectoris (chronic stable angina pectoris, unstable angina), myocardial infarction, ischemic cerebrovascular disorder (transient ischaemic attack (TIA), cerebral infarction)• After coronary artery bypass grafting (CABG) or percutaneous transluminal coronary angioplasty (PTCA)
d.	Aspirin/lansoprazole	Takelda Combination Tablets	T's Pharma Co., Ltd.	June 2014	<p>Prevention of thrombus/embolus formation in the following diseases or after surgery (limited to patients with a history of gastric ulcer or duodenal ulcer):</p> <ul style="list-style-type: none">• Angina pectoris (chronic stable angina pectoris, unstable angina), myocardial infarction, ischemic cerebrovascular disorder (transient

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					ischaemic attack (TIA), cerebral infarction) • After coronary artery bypass grafting (CABG) or percutaneous transluminal coronary angioplasty (PTCA)
e.	Clopidogrel sulfate/aspirin	ComPlavin Combination Tablets, etc.	Sanofi K.K., etc. and the others	December 2013	The following ischaemic heart diseases for which percutaneous coronary Intervention (PCI) is indicated: <input type="radio"/> Acute coronary syndromes (unstable angina, non-ST elevation myocardial infarction, ST-elevation myocardial infarction) <input type="radio"/> Stable angina pectoris, old myocardial infarction
f.	Aspirin (preparations indicated for antipyresis/analgesia/anti-inflammation)	Aspirin "Maruishi", etc.	Maruishi Pharmaceutical Co., Ltd. and the others	October 1950*	<input type="radio"/> Rheumatoid arthritis, rheumatic fever, osteoarthritis, ankylosing spondylitis, periarthritis, fibrositis, postoperative pain, toothache, symptomatic neuralgia, arthralgia, lumbago, myalgia, pain caused by sprain, contusion, and gout, headache, painful menses <input type="radio"/> Antipyresis/analgesia in the following diseases: Acute upper respiratory tract inflammation (including acute upper respiratory tract inflammation accompanied by acute bronchitis) <input type="radio"/> Kawasaki disease (including cardiovascular sequelae of Kawasaki disease)

* For active ingredients for which the brand name product is not marketed, if a product which has an older date of Japanese market launch than that of the product described in the "Brand name" column is confirmed in package inserts, etc., such a date is described.

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