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Summary of Investigation Results

Preparations containing aspirin or aspirin aluminum (OTC drug)

January 13, 2026

Non-proprietary name

- a. Preparations containing aspirin
- b. Preparations containing aspirin aluminum

Brand name (marketing authorization holder)

- a.-1 Bufferin A (Lion Corporation) and other OTC drugs
- a.-2 New Asunamin Z (SATO YAKUHI KOGYO Co.,Ltd.) and other OTC drugs
- b. -

Japanese market launch

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Indications

- a.-1 Analgesia for headache, painful menses (period pains), arthralgia, neuralgia, low back pain, myalgia, pain associated with shoulder muscle stiffness, sore throat, toothache, pain after tooth extraction, bruising pain, sprain pain, fracture pain, traumatic pain, ear pain
Antipyresis for chills or pyrexia
- a.-2 Relief of symptoms of cold (nasal discharge, nasal congestion, sneezing, sore throat, cough, sputum, chills (chilliness due to pyrexia), pyrexia, headache, arthralgia, myalgia)
- b. -

Summary of revisions

"Acute coronary syndrome accompanying allergic reaction" should be added to the



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Consultation section.

Investigation results and background of the revision

As a result of consultation with expert advisors, since the PRECAUTIONS of the prescription drugs will be revised, the MHLW/PMDA concluded that a similar revision of PRECAUTIONS was necessary for the OTC drugs.

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