



Summary of Investigation Results

NSAIDs for which systemic effects are expected (OTC drugs, guidance-mandatory drugs)

October 8, 2024

Non-proprietary name

- a. Preparations containing aspirin
- b. Preparations containing ibuprofen
- c. Preparations containing naproxen
- d. Preparations containing loxoprofen sodium hydrate

Brand name (marketing authorization holder)

- a-1 Bufferin A (Lion Corporation) and other OTC drugs
- a-2 New Asunamin Z (SATO YAKUHHIN KOGYO Co., Ltd.) and other OTC drugs
- b-1 Eve-A Tablets (SSP Co., Ltd.) and other OTC drugs
- b-2 Pabron Ace Pro-X Granules (Taisho Pharmaceutical Co., Ltd.) and other OTC drugs
- c. Motrin NX (JNTL Consumer Health K.K.)
- d.-1 Loxonin S (Daiichi Sankyo Healthcare Co., Ltd.) and other OTC drugs
- d.-2 Loxonin Common cold medicine (Daiichi Sankyo Healthcare Co., Ltd.) and other guidance-mandatory drugs

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, b.-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.-1

1) Analgesia for headache, toothache, pain after tooth extraction, sore throat, ear pain, arthralgia, neuralgia, low back pain, myalgia, pain associated with shoulder muscle stiffness, bruising pain, fracture pain, sprain pain, painful menses (period pains), traumatic pain

2) Antipyresis for chills or pyrexia

c.

Analgesia for headache, toothache, pain after tooth extraction, sore throat, ear pain, arthralgia, neuralgia, low back pain, myalgia, pain associated with shoulder muscle stiffness, bruising pain, fracture pain, sprain pain, painful menses (period pains), traumatic pain

Antipyresis for chills or pyrexia

d.-1

- Analgesia for headache, toothache, pain after tooth extraction, sore throat, ear pain, arthralgia, neuralgia, low back pain, myalgia, pain associated with shoulder muscle stiffness, bruising pain, fracture pain, sprain pain, painful menses (period pains), traumatic pain

- Antipyresis for chills or pyrexia

d.-2

Relief of symptoms of cold (nasal discharge, nasal congestion, sneezing, throat pain, cough, sputum, chills, pyrexia, headache, arthralgia, myalgia)

Summary of revisions

a. The necessity of taking safety measures regarding myocardial infarction and cerebrovascular disorder was evaluated.

b.-d.

“Myocardial infarction” and “cerebrovascular disorder” should be added to the Consultation section.

Investigation results and background of the revision

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As a result of consultation with expert advisors, since the PRECAUTIONS of NSAID prescription drugs (excluding aspirin) for which systemic effects are expected will be revised, the MHLW/PMDA concluded that a similar revision of PRECAUTIONS was necessary for the OTC drugs and guidance-mandatory drugs.

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).