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Summary of Investigation Results

Preparations containing loxoprofen sodium hydrate (oral dosage form) (OTC drugs)

October 12, 2022

Non-proprietary name

Loxoprofen sodium hydrate

Brand name (Marketing authorization holder)

Loxonin S, Loxonin S Quick, Loxonin S plus, Loxonin S Premium (Daiichi Sankyo Healthcare Co., Ltd.), and the other OTC drugs

Indications

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

·Antipyresis of chills or pyrexia

Summary of revisions

“Acute generalised exanthematous pustulosis” should be added to the Consultation section.

Investigation results and background of the revision

Acute generalised exanthematous pustulosis will be newly added in the Precautions for the prescription drug of preparations containing loxoprofen sodium hydrate. As a result of consultation with expert advisors, MHLW/PMDA concluded that similar revision of Precautions was necessary for the OTC drugs.

Pharmaceuticals and Medical Devices Agency

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Number of cases and patient mortalities involving acute generalized exanthematous pustulosis reported in Japan during the previous 3 fiscal years

No cases have been reported to date.

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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