This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results

Loxoprofen sodium hydrate (oral dosage form) (prescription drug)

October 12, 2022

Non-proprietary name

Loxoprofen sodium hydrate

Brand name (Marketing authorization holder)

Loxonin Tablets 60 mg, Loxonin Fine Granules 10% (Daiichi Sankyo Co., Ltd.), and the others

Indications

- Anti-inflammation/analgesia in the following diseases and symptoms:
  Rheumatoid arthritis, osteoarthritis, lumbago, periarthritis scapulohumeralis, neck, shoulder and arm syndrome, toothache
- Post-operative, post-traumatic, or post-tooth extraction anti-inflammation/analgesia
- Antipyresis/analgesia in the following diseases:
  Acute upper respiratory tract inflammation
  (including acute upper respiratory tract inflammation accompanied by acute bronchitis)

Summary of revisions

“Acute generalised exanthematous pustulosis” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases involving acute generalised exanthematous pustulosis reported in Japan were evaluated. Cases for which a causal relationship between loxoprofen sodium hydrate and acute generalised exanthematous pustulosis was reasonably possible have been reported

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in Japan. As a result of consultation with expert advisors, MHLW/PMDA concluded that revision of Precautions was necessary.

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

A total of 17 cases involving acute generalised exanthematous pustulosis have been reported to date (including 3 cases for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities 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).