



Summary of investigation results

Loxoprofen sodium hydrate

(for oral use)

March 22, 2016

Non-proprietary name

Loxoprofen sodium hydrate (for oral use)

Brand name (Marketing authorization holder)

Loxonin Tablets 60 mg, Loxonin Fine Granules 10 % (Daiichi Sankyo Co., Ltd), Loxoprofen Sodium Oral Solution 60 mg (Nichi-Iko Co., Ltd)., and the others

Indications

1. Anti-inflammatory/Analgesic for the following diseases and symptoms
Rheumatoid arthritis, osteoarthritis, lumbago, periartthritis scapulohumeralis, neck, shoulder and arm syndrome, toothache
2. Analgesic/Anti-inflammatory for post-surgery, post-trauma, and after tooth extraction
3. Antipyretic/Analgesic for the following diseases
Acute upper respiratory inflammation (including acute upper respiratory inflammation associated with acute bronchitis)

Summary of revision

“Stenosis and obstruction of small intestine and large intestine” should be newly added in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of stenosis and obstruction of small intestine and large intestine have been reported in patients treated with loxoprofen sodium hydrate in Japan. Following an investigation



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result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 6 cases associated with stenosis and obstruction of small intestine and large intestine have been reported (including 5 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.