This English version is intended to be a reference material for the convenience of 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 (dermatologic preparation) (guidance-mandatory drugs)

July 4, 2017

Non-proprietary name

Loxoprofen sodium hydrate (dermatologic preparation)

Brand name (Marketing authorization holder)

Loxonin S Poultice, Loxonin S Tape, Loxonin S Tape L (Lead Chemical Co., Ltd.), Loxonin S Gel (Daiichi Sankyo Healthcare Co., Ltd.)

Indications

Low back pain, shoulder pain associated with shoulder muscle stiffness, arthralgia, myalgia, tenosynovitis (hand and wrist pain), aching pain in elbows (tennis elbow, etc.), bruise, sprain

Summary of revision

“Shock (anaphylaxis)” should be added in the Consultation section.

Background of the revision and investigation results

“Shock, anaphylaxis” will be newly added in the package insert for the prescription products of loxoprofen sodium hydrate. Following investigation results based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that similar revisions of the package insert were necessary for the guidance-mandatory products.

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

No cases associated with shock or anaphylaxis have been reported.

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