



# Summary of investigation results

## Loxoprofen sodium hydrate (dermatologic preparation)

July 4, 2017

### **Non-proprietary name**

Loxoprofen sodium hydrate (dermatologic preparation)

### **Brand name (Marketing authorization holder)**

Loxonin Pap 100 mg, Loxonin Tape 50 mg, 100 mg (Lead Chemical Co., Ltd.), Loxonin Gel 1% (Daiichi Sankyo Co., Ltd.), Loxoprofen Na Spray 1% YD (Yoshindo Inc.), and others

### **Indications**

Anti-inflammation/Pain relief in the following diseases and symptoms  
Osteoarthritis, myalgia, post-traumatic pain/swelling

### **Summary of revision**

The Clinically Significant Adverse Reactions subsection should be newly added in the Adverse Reactions section in the package insert, and “shock, anaphylaxis” should be added.

### **Background of the revision and investigation results**

Cases of shock or anaphylaxis have been reported in patients treated with loxoprofen sodium hydrate in Japan. Following investigation results 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**



*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.*

A total of 6 cases associated with shock or anaphylaxis have been reported (including 2 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.