

# Summary of investigation results

## Products containing loxoprofen sodium hydrate (OTC drugs for oral use)

March 22, 2016

### **Non-proprietary name**

Products containing loxoprofen sodium hydrate (OTC drugs for oral use)

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

Loxonin S (Daiichi Sankyo Healthcare Co., Ltd.), and the others

### **Indications**

Relief of pain for headaches, painful menses (period pains), toothache, pain after tooth extraction, sore throat, low back pain, arthralgia, neuralgia, myalgia, shoulder pain associated with shoulder muscle stiffness, ear pain, bruising pain, fracture pain, sprain pain, and traumatic pain; antipyretic for chills or pyrexia.

### **Summary of revision**

“Stenosis and obstruction of small intestine and large intestine” should be newly added in the Consultation section.

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

Stenosis and obstruction of small intestine and large intestine will be newly added in the package insert for the prescription product of loxoprofen sodium hydrate. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that similar revisions of the package insert was necessary for the OTC drugs.

**Pharmaceuticals and Medical Devices Agency**

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

No case associated with stenosis and obstruction of small intestine and large intestine has been reported.

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