



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.

Revision of Precautions

Loxoprofen sodium hydrate

(for oral use)

March 22, 2016

Non-proprietary name

Loxoprofen sodium hydrate (for oral use)

Safety measure

Precautions should be revised in the package insert.

In the Clinically significant adverse reaction subsection of the Adverse reaction section, the following text should be added (underlined parts are revised):

Stenosis and obstruction of small intestine and large intestine:

Stenosis or obstruction of small intestine or large intestine may occur in association with small intestine or large intestine ulcers. Patients should be carefully monitored. If any symptoms such as nausea and vomiting, abdominal pain, and abdominal distention are observed, administration of this drug should be discontinued immediately and appropriate measures should be adopted.

* Loxoprofen sodium hydrate is designated as a drug requiring preparation of a Drug Guide for Patients.