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Revision of Precautions
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)

Safety measure

Precautions should be revised in the package insert.

In the Consultation section, the following text should be revised (underlined parts are revised):

If the following symptoms are observed after taking this drug, immediately discontinue use of this drug as these may be adverse reactions, and show this document to your physician or pharmacist for consultation.

Occurrence of peptic ulcers or oedema after administration of the drug

In addition, severe symptoms such as gastrointestinal haemorrhage (associated with symptoms such as haematemesis, nausea and vomiting, abdominal pain, black tar-like stool, and bloody stool), gastrointestinal perforation (indicates a hole in the gastrointestinal area, and associated with symptoms such as nausea and vomiting and severe abdominal pain), and stenosis or obstruction of small intestine or large intestine (associated with symptoms such as nausea and vomiting, abdominal pain, and abdominal distension) may rarely occur. In such cases, immediately seek medical attention.

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