



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 (dermatologic preparation)

July 4, 2017

Non-proprietary name

Loxoprofen sodium hydrate (dermatologic preparation)

Safety measure

Precautions should be revised in the package insert.

The Clinically Significant Adverse Reactions subsection should be newly added in the Adverse Reactions section of the package insert and the following text should be added (underlined parts are revised):

Shock, anaphylaxis:

Shock or anaphylaxis (decreased blood pressure, urticaria, laryngeal oedema, dyspnoea, etc.) may occur. Patients should be carefully monitored. If any abnormalities are observed, use of this drug should be discontinued immediately and appropriate measures should be taken.