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Pharmaceuticals and Medical Devices Agency



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 (oral dosage form) (prescription drug)

October 12, 2022

Therapeutic category

Antipyretics, analgesics and anti-inflammatory agents

Non-proprietary name

Loxoprofen sodium hydrate

Safety measure

Precautions should be revised.

Pharmaceuticals and Medical Devices Agency

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
<p>Adverse Reactions</p> <p>Clinically Significant Adverse Reactions</p> <p>Toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome), erythema multiforme: Toxic epidermal necrolysis, oculomucocutaneous syndrome, or erythema multiforme may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued immediately, and appropriate measures should be taken.</p>	<p>Adverse Reactions</p> <p>Clinically Significant Adverse Reactions</p> <p>Toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome), erythema multiforme, <u>acute generalised exanthematous pustulosis</u>: Toxic epidermal necrolysis, oculomucocutaneous syndrome, erythema multiforme, <u>or acute generalised exanthematous pustulosis</u> may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued immediately, and appropriate measures should be taken.</p>

Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): Revised language is underlined.

Current	Revision
<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome), erythema multiforme</p>	<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome), erythema multiforme, <u>acute generalised exanthematous pustulosis</u></p>

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