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Pharmaceuticals and Medical Devices Agency

Revision of Precautions
Diclofenac etalhyaluronate sodium

June 1, 2021

Therapeutic category

Agents affecting metabolism, n.e.c. (not elsewhere classified)

Non-proprietary name

Diclofenac etalhyaluronate sodium

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
(N/A)	1. WARNINGS Serious shock and anaphylaxis may occur following administration of this drug. Sufficient preparation for emergency responses should be ensured prior to administration. Patients should be carefully monitored after administration of this drug.
8. IMPORTANT PRECAUTIONS (N/A)	8. IMPORTANT PRECAUTIONS Serious shock and anaphylaxis may occur following administration of this drug. Sufficient preparation for emergency responses should be ensured prior to administration. Patients should be carefully monitored during and after administration of this drug. Patients and their caregivers, etc., should be adequately informed that shock and anaphylaxis may occur, with signs and symptoms, and that patients should seek medical attention immediately if any abnormalities are observed.

N/A: Not Applicable, because the section is not included in the current package insert or no corresponding language is included in the section.

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