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Revision of Precautions

Allopurinol

February 25, 2020

Therapeutic category

Gout preparations

Non-proprietary name

Allopurinol

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, 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
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions Aseptic meningitis: Aseptic meningitis accompanied by symptoms such as nuchal rigidity, pyrexia, headache, nausea and vomiting, or disturbed consciousness may occur. Cases of aseptic meningitis that developed several hours after the administration of this drug have been reported.

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
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Aseptic meningitis: Aseptic meningitis accompanied by symptoms such as nuchal rigidity, pyrexia, headache, nausea and vomiting, or disturbed consciousness may occur. Cases of aseptic meningitis that developed several hours after the administration of this drug have been reported.

N/A: Not Applicable, because the section is not included in the current package insert.

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