



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 Allopurinol

November 22, 2016

Non-proprietary name

Allopurinol

Safety measure

Precautions should be revised in the package insert.

In the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section, the following text should be added (underlined parts are revised):

Drug-induced hypersensitivity syndrome (DIHS): Serious late-onset severe hypersensitivity symptoms may occur. Rash and/or pyrexia occur as initial symptoms, followed by lymphadenopathy, increased white blood cell count, increased eosinophil count, atypical lymphocytes, and organ damage such as hepatic function disorder. Among case reports associated with DIHS, there have been reports of cases developing type 1 diabetes mellitus (including fulminant type 1 diabetes mellitus) resulting in ketoacidosis. Patients should be carefully monitored. If any abnormalities are observed, the administration of this drug should be discontinued and appropriate measures should be adopted. The reactivation of viruses including Human Herpes Virus 6 (HHV-6) has been frequently found to be associated with DIHS. Even after the discontinuation of administration, symptoms, such as rash, pyrexia, and/or hepatic function disorder, may relapse or be prolonged, and symptoms of disorder in central nervous system such as encephalitis may occur. Therefore, patients should continue to be carefully monitored.

Reference

Manuals for management of individual serious adverse drug reaction – Drug-induced hypersensitivity syndrome (Ministry of Health, Labour, and Welfare)

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