This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of investigation results

Allopurinol

November 22, 2016

Non-proprietary name

Allopurinol

Brand name (Marketing authorization holder)

Zyloric Tablets 50 mg, 100 mg (GlaxoSmithKline K.K.), and the others

Indications

Management of hyperuricemia in patients with gout or in hypertensive patients with hyperuricemia

Summary of revision

Precautions with regard to “drug-induced hypersensitivity syndrome” should be added in the Clinically Significant Adverse Reactions section and “type 1 diabetes mellitus (including fulminant type 1 diabetes mellitus) resulting in ketoacidosis” should be added to the text in the section.

Background of the revision and investigation results

Cases of type 1 diabetes mellitus related to drug-induced hypersensitivity syndrome have been reported in patients treated with allopurinol in Japan. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary, though the Clinically Significant Adverse Reactions section included the description of “hypersensitivity syndrome”.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 2 cases associated with type 1 diabetes mellitus related to drug-induced

hypersensitivity syndrome have been reported (including 1 case for which a causal relationship to the product could not be ruled out). Two fatal cases have been reported (including no fatal cases for which a causal relationship to the product could not be ruled out*).

NOTE:

* fatal cases for which a causal relationship between the reported adverse reaction and death could not be ruled out.

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp