



Summary of Investigation Results

Allopurinol

February 25, 2020

Non-proprietary name

Allopurinol

Branded 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 hypertension accompanied by hyperuricemia

Summary of revisions

“Aseptic meningitis” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of aseptic meningitis have been reported in patients treated with allopurinol in Japan and overseas. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.



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.

Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

No cases involving aseptic meningitis have been reported to date.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).