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Revision of Precautions

Febuxostat

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Therapeutic category

Gout preparations

Non-proprietary name

Febuxostat

Safety measure

Precautions should be revised in the package insert.

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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
Important Precautions (N/A)	Important Precautions An overseas clinical study has shown that the incidence of cardiovascular death was higher in the febuxostat group than the allopurinol group in patients with gout who had cardiovascular disease. Caution is required for exacerbation or novel onset of cardiovascular diseases when febuxostat is administered.
Other Precautions (N/A)	Other Precautions A double-blind, non-inferiority study was conducted overseas in patients with gout who had cardiovascular disease. Results showed that febuxostat was non-inferior to allopurinol for the primary endpoint (a composite endpoint composed of cardiovascular death, nonfatal myocardial infarction, nonfatal cerebral stroke, and urgent revascularization for unstable angina). However, of the secondary endpoints, the incidence of cardiovascular death was 4.3% (134/3098 patients) in the febuxostat group, higher than 3.2% (100/3092 patients) in the allopurinol group (hazard ratio [95%CI]: 1.34 [1.03, 1.73]). Among cardiovascular deaths, sudden cardiac death was most commonly observed in both groups (febuxostat group: 2.7% (83/3098 patients), allopurinol group 1.8% (56/3092 patients).) The incidence of all-cause death in the febuxostat group

	and in the allopurinol group was 7.8% (243/3098 patients) and 6.4% (199/3092 patients), respectively, higher in the febuxostatgroup (HR was 1.22 [95%CI: 1.01-1.47].)

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