

Table S1 Inclusion and Exclusion Criteria

A. Inclusion criteria

1. Gout patients with uric acid level over 7.0 mg/dL who are not under treatment with any uric-acid lowering drugs
 2. Patients who had gouty arthritis in the last 12 months
 3. Patients are male and aged 20 years or older at the time of acquisition of informed consent
 4. Patients who are not hospitalized (out-patient status)
 5. Patients who consent in writing to participate in the study
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B. Exclusion criteria

1. Patients who have previous history of hypersensitivity to febuxostat
 2. Patients who have previous history of hypersensitivity to colchicine
 3. Patients who have previous history of hypersensitivity to NSAIDs or patients who have not been affected by NSAIDs
 4. Patients who had gouty arthritis in the last 2 weeks
 5. Patients who have used any uric-acid lowering drugs in the last 4 weeks
 6. Patients with secondary hyperuricemia
 7. Patients who have twice as high AST or ALT as the hospital's reference value
 8. Patients with serum creatinine level of 2.0 mg/dL or higher
 9. Patients who have or have had past history of malignant tumor as a complication requiring treatment
 10. Patients who are being treated with either mercaptopurine hydrate or azathioprine
 11. Patients with peptic ulcer
 12. Patients with serious hematological disorder
 13. Patients with serious cardiac disorder
 14. Patients with aspirin-induced asthma or its previous history
 15. Patients who participated in another clinical study or clinical trial in the 6 months prior to the confirmation of eligibility
 16. Patients who are ineligible for the study as judged by the attending investigator
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Table S2 Incidences of gout flares in patients with or without previous treatments with urate-lowering drugs

Group	Previous treatment by urate lowering drug		p-value*
	-	+	
	Incidence (n/N)	Incidence (n/N)	
Group A (N=96)	0.169 (11/65)	0.290 (9/31)	0.273
Group B (N=95)	0.188 (12/64)	0.194 (6/31)	1.000
Group C (N=50)	0.353 (12/34)	0.375 (6/16)	1.000
Total	0.215 (35/163)	0.269 (21/78)	0.439

* Chi square test

Figure S1 Number of gout flares during the 24 weeks (randomised + observation period)

