

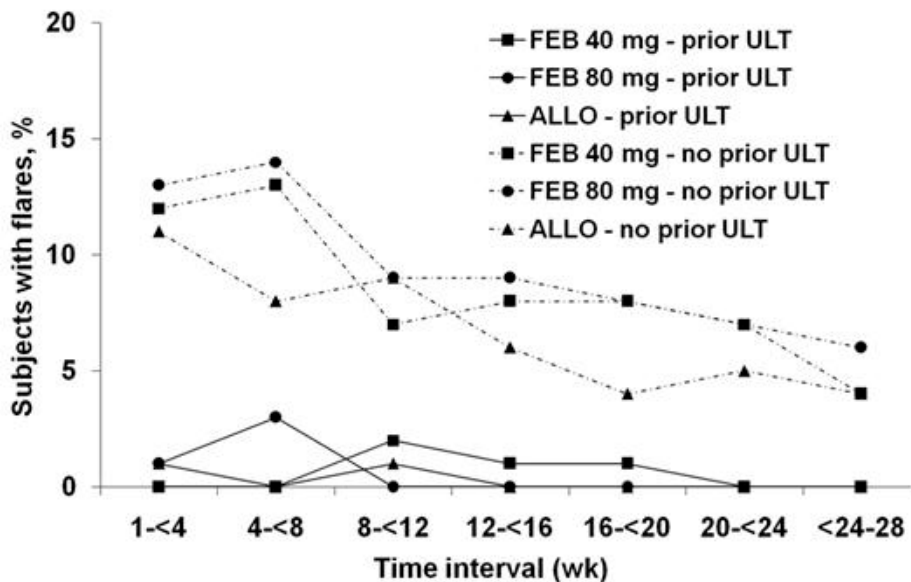
## DOCUMENTATION OF FEWER GOUT FLARES AFTER LONG-TERM URATE LOWERING THERAPY

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Compare efficacy, gout flare rates, and safety of 6-month febuxostat or allopurinol treatment between subjects whose gout and hyperuricemia was successfully treated in prior trials with febuxostat or allopurinol for 3-5 years vs subjects not previously so treated.

**Methods:** In the 6-month CONFIRMS trial, 2269 subjects with gout and hyperuricemia received daily febuxostat 40 or 80 mg or allopurinol (300 or 200 mg based on creatinine clearance). There were 276 subjects from the previous FOCUS (5 yrs) or EXCEL (3 yrs) trials maintaining serum urate level (sUA) <6 mg/dL for up to 5 yrs on febuxostat 40, 80, or 120 mg or allopurinol 300 mg. Randomization was stratified by renal function and prior long-term urate-lowering therapy (ULT) study participation. Subjects with ongoing ULT washed out for  $\geq 30$  days and had baseline sUA  $\geq 8$  mg/dL before entering CONFIRMS. Subjects received colchicine or naproxen for gout flare prophylaxis.

**Results:** Demographics in this prior treatment subset were similar to those of the entire group. Proportions of subjects with prior participation who achieved sUA <6 mg/dL at final visit in the febuxostat 40 or 80 mg and allopurinol groups were 57%, 77%, and 52%, respectively, vs 43%, 66%, and 41%, respectively, among subjects without prior participation ( $p \leq 0.05$ ). Overall, subjects with prior participation in each group had lower flare rates ( $p < 0.001$ ) vs those without prior participation (figure). The most frequent AEs were URIs, abnormal LFTs, musculoskeletal pain, and diarrhea, and rates of AEs were similar among subjects with and without prior participation.  
**Conclusions:** The subset with 3-5 yrs of prior ULT achieved sUA <6 mg/dL more often and had substantially fewer reported gout flares vs subjects without prior long-term ULT. This demonstrates the clinical benefit of maintaining sUA <6 mg/dL in reducing subsequent gout flare incidence.



**Figure.** Proportion of subjects receiving gout flare treatment.