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THE EFFICACY OF ROFECOXIB VERSUS NAPROXEN IN OSTEOARTHRITIS: SUBGROUP ANALYSIS BY JOINT IN THE ADVANTAGE TRIAL

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To evaluate comparative osteoarthritis (OA) efficacy in the ADVANTAGE trial, a study examining the gastrointestinal (GI) tolerability of rofecoxib and naproxen in the treatment of patients with various primary sites of OA during a 12-week period. Patients meeting entry criteria (non-flare design) were randomized to receive rofecoxib 25 mg qd (n=2785) or naproxen 500 mg bid (n=2772). The primary endpoint was GI tolerability as defined by the incidence of discontinuations due to GI adverse experiences (AEs). OA efficacy was assessed in all patients by Patient Global Assessment of Disease Status (PGADS; a 0-100 mm visual analog scale), discontinuations due to lack of efficacy (LOE), and, in hand OA patients, also by the AUSCAN OA Hand Index, (three domains: pain, stiffness, and function) scored on a 5-point Likert Scale). Baseline characteristics were similar between treatment groups. The primary sites of OA were: knee (50%), spine (24%), hand (16%), and hip (10%). Between treatments efficacy similarity was maintained in subgroup analyses performed by joint. In patients treated for three months, rofecoxib 25 mg qd demonstrated superior GI tolerability compared to naproxen 500 mg bid, while exhibiting a similar efficacy profile when assessing the entire cohort as well as across all primary sites of OA.

None

Endpoint	Rofecoxib	Naproxen	P value
PGADS Mean Change Wk 6	-11.6 mm	-10.8 mm	NS
PGADS Mean Change WK 12	-10.4 mm	-9.6 mm	NS
AUSCAN Pain Mean Change Wk 12	-0.28	-0.31	NS
AUSCAN Stiffness Mean Change Wk 12	-0.39	-0.33	NS
AUSCAN Function Mean Change Wk 12	-0.37	-0.38	NS
Discons. Due to LOE	6.4%	6.3%	NS
Discons. Due to GI AEs	5.9%	8.1%	0.005
Between treatments efficacy similarity was maintained in subgroup analyses by joint.			