

2002 Fall A14

TREATMENT OF CHRONIC LOW BACK PAIN WITH ETORICOXIB, A NEW CYCLO-OXYGENASE-2 SELECTIVE INHIBITOR: A 3-MONTH PLACEBO-CONTROLLED TRIAL

Geba, G.P.1; Seger, W.2; Adler, J.3; Ettliger, R.4; Quaidoo, E.5; Lipetz, R.6; Pallay, R.7; Petruschke, R.A.1; Bohidar, N.1

1. Clinical Development, Merck & Co., West Point, PA; 2. Benchmark Research, Fort Worth, TX; 3. Clinicos, Colorado Springs, CO; 4. Private Practice, Tacoma, WA; 5. AAIR Research Center, Rochester, NY; 6. Encompass Clinical Research, Spring Valley, CA; 7. Robert Wood Johnson University Medical Group, Hillsborough, NJ

We evaluated the efficacy of etoricoxib 60 mg and 90 mg for the treatment of chronic low back pain (LBP). A total of 325 patients were assigned to receive daily etoricoxib 60 mg (n=109) or 90 mg (n=106), or placebo (n=110) in a randomized, placebo-controlled 3 month trial. Patients were then assessed at office visits at 1, 2, 4, 8, and 12 weeks. The primary endpoint was improvement from baseline in time-weighted average LBP Intensity Scale (0- to 100-mm Visual Analog Scale) at 4 weeks, which was also evaluated over 3 months with other outcome parameters. Demographics were similar among treatment groups. Patients ranged in age from 19 to 78 years (mean 53 years). Average duration of LBP was 12 years. Etoricoxib 60 mg [-34.4 (CI: -38.7, -30.1)] and 90 mg [-32.3 (CI: -36.6, -27.9)] both demonstrated significant ($P<.001$) improvement vs. placebo [-19.3 (CI: -23.5, -15.0)] for LBP intensity at 4 weeks, which was maintained over 3 months [-35.1 (CI: -39.6, -30.7), -35.7 (CI: -40.2, -31.2) vs. -23.0 (CI: -27.4, -18.6), respectively] ($P<.001$). Other endpoints including disability and bothersomeness scores paralleled pain relief. In patients with chronic LBP, etoricoxib at doses of 60 and 90 mg daily provided significant efficacy in relief of pain and disability over the course of 3 months. Improvement was observed as early as 1 week after initiation of therapy; plateaued at 4 weeks; and was maintained over the 3 months of the trial. All treatments were generally well tolerated.