

PubMed

Display Settings: Abstract

Clin Ther. 2008 Nov;30(11):1988-2004. doi: 10.1016/j.clinthera.2008.11.009.

Milnacipran for the treatment of fibromyalgia in adults: a 15-week, multicenter, randomized, double-blind, placebo-controlled, multiple-dose clinical trial.

Clauw DJ¹, Mease P, Palmer RH, Gendreau RM, Wang Y.

Author information

¹Department of Anesthesiology, Chronic Pain and Fatigue Research Center, University of Michigan Medical School, Ann Arbor, Michigan 48106, USA. dclauw@umich.edu

Erratum in

Clin Ther. 2009 Feb;31(2):446.

Clin Ther. 2009 Jul;31(7):1617.

Abstract

BACKGROUND: Preclinical and clinical studies have suggested that milnacipran, a dual norepinephrine-serotonin reuptake inhibitor, may be efficacious in the treatment of fibromyalgia (FM).

OBJECTIVE: This study was conducted to evaluate the efficacy and tolerability of milnacipran in treating the multiple domains of FM.

METHODS: This was a multicenter, double-blind, placebo-controlled trial. Adult patients (age 18-70 years) who met 1990 American College of Rheumatology criteria for FM were randomized to receive milnacipran 100 mg/d, milnacipran 200 mg/d, or placebo for 15 weeks. Because this was a pivotal registration trial, the primary end points were chosen to investigate efficacy for 2 potential indications: the treatment of FM and the treatment of FM pain. Thus, the 2 primary efficacy end points were rates of FM composite responders and FM pain composite responders. FM composite responders were defined as patients concurrently experiencing clinically meaningful improvements in the following 3 domain criteria: pain (> or = 30% improvement, as recorded in an electronic diary); patients' global status (a rating of very much improved or much improved on the Patient Global Impression of Change [PGIC] scale); and physical function (a > or = 6-point improvement on the 36-item Short-Form Health Survey [SF-36] Physical Component Summary score). FM pain composite responders were defined as those who met the pain and PGIC criteria. Adverse events reported by patients or observed by investigators were recorded throughout the trial.

RESULTS: Of 2270 patients screened, 1196 were randomized to receive milnacipran 100 mg/d (n = 399), milnacipran 200 mg/d (n = 396), or placebo (n = 401). The majority of patients were female (96.2%) and white (93.5%). The population had a mean age of 50.2 years, a mean baseline weight of 180.8 pounds, and a mean baseline body mass index of 30.6 kg/m². Compared with placebo, significantly greater proportions of milnacipran-treated patients were FM composite responders (100 mg/d: P = 0.01; 200 mg/d: P = 0.02) and FM pain composite responders (100 mg/d: P = 0.03; 200 mg/d: P = 0.004). Milnacipran was associated with significant improvements in pain after 1 week of treatment (100 mg/d: P = 0.004; 200 mg/d: P = 0.04), as well as significant improvements in multiple secondary efficacy end points, including global status (PGIC: P < 0.001 for both doses), physical function (SF-36 physical functioning domain-100 mg/d: P < 0.001; 200 mg/d: P = 0.02), and fatigue (Multidimensional Fatigue Inventory- 100 mg/d: P = 0.04). The most commonly reported

adverse events with milnacipran were nausea (100 mg/d, 34.3%; 200 mg/d, 37.6%), headache (18.0% and 17.7%, respectively), and constipation (14.3% and 17.9%). Adverse events resulted in premature study discontinuation in 19.5% and 23.7% of those who received milnacipran 100 and 200 mg/d, respectively, compared with 9.5% of placebo recipients.

CONCLUSION: In these adult patients with FM, both doses of milnacipran (100 and 200 mg/d) were associated with significant improvements in pain and other symptoms. Clinical Trials Identification Number: [NCT00098124](#).

PMID: 19108787 [PubMed - indexed for MEDLINE]



Publication Types, MeSH Terms, Substances, Secondary Source ID 

LinkOut - more resources 

PubMed Commons

[PubMed Commons home](#)

 0 comments

[How to join PubMed Commons](#)