A Three-Year, Open-Label, Flexible-Dosing Study of Milnacipran for the Treatment of Fibromyalgia

Introduction

Fibromyalgia (FM) is characterized by widespread pain and multiple tender points that are not alleviated by exercise or rest in a defined period of time.1 This chronic, debilitating pain condition is associated with several co-morbidities, including sleep disturbances.2 Patients with FM experience substantial physical and mental disabilities, reduced quality of life, and are associated with increased healthcare costs.3-5 Milnacipran (Nefyzol®; Forest Laboratories Inc.) is a non-opioid analgesic with serotonin–norepinephrine reuptake inhibitors (SNRI) properties.6 Milnacipran improves pain in patients with FM (as measured by the total and average tender-point scores, the total and average pain scores, and the visual analog scale) in most placebo-controlled studies.1,2,7-10 Milnacipran’s safety and tolerability profile are well established and its use is not associated with significant drug-drug interactions.11-13

Objective

The objective of this study was to assess the safety, efficacy, and tolerability of milnacipran in patients with FM in a long-term open-label study. The study design was FM in a long-term open-label study. To assess the long-term efficacy, safety, and tolerability of milnacipran in patients with FM for more than 1 year.

Study Design

FM in a long-term open-label study. To assess the long-term efficacy, safety, and tolerability of milnacipran in patients with FM is sustained for more than 1 year.

Methods

Patients were selected using a number of inclusion criteria to allow a variance in the patient population. The inclusion criteria included the following: at least 18 years of age, FM diagnosis determined by American College of Rheumatology criteria, and were sustained for the entire study (up to 3.25 years in the study).

Results

The cohort of patients who completed ≥3 years in this study had slightly greater improvement from baseline in SF-36 PCS than the overall ITT population (which included previous milnacipran study or were active in a milnacipran study when it was administratively complete). The results were consistent with previous experience with milnacipran in shorter placebo-controlled trials.10

Conclusions

There are new findings for the sustained use of milnacipran for the treatment of FM.

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Adverse Events

The most common adverse events (AEs) occurring in 20% or patients were somnolence (29.9%), gastrointestinal disturbance (27.9%), nausea (24.6%), and urinary tract infection (16.3%). The rates of discontinuation due to AEs were 28.9%, 15.1%, 14.1%, 13.6%, and 9.3%, respectively. With the exception of gastrointestinal disturbance, the rates of discontinuation due to AEs were lower than had been reported in previous milnacipran studies.

References