Pregabalin Is First Drug Approved for Fibromyalgia

By Elizabeth Mechcatie Senior Writer

Pregabalin has become the first drug to win approval by the Food and Drug Administration for the management of fibromyalgia. The FDA based the approval on two double-blind, placebo-controlled trials involving approximately 1,800 patients. Data from the studies have shown that patients with fibromyalgia “have decreased pain after taking [pregabalin], but, the mechanism by which [pregabalin] produces such an effect is unknown,” according to an agency-issued statement.

In the clinical trials of patients with fibromyalgia, those on pregabalin (Lyrica) had “rapid and sustained improvements in pain,” compared with those on placebo, and “reported feeling better and improved function,” according to a statement issued by Pfizer, which manufactures pregabalin. The same statement explains that the drug’s mechanism of action for fibromyalgia is not known, but states that patients with fibromyalgia may be more sensitive than normal to stimuli that are not usually painful, and that pregabalin may reduce the degree of pain experienced by patients with fibromyalgia by binding to a specific protein within nerve cells.

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According to the revised prescribing information for pregabalin, the two studies—a 14-week double-blind placebo-controlled study and a 6-month randomized with-drawal study—found that treatment was associated with a reduction in pain by visual analog scale and improvements based on a patient global assessment and the Fibromyalgia Impact Questionnaire.

In the 14-week study, some patients experienced reductions in pain during the first week of treatment, which continued throughout the study. Nearly 70% of those on a total daily dose of 300 mg of pregabalin, and 78% of those on a total daily dose of 450 mg, reported improvement from the Fibromyalgia Impact Questionnaire.

The patients were divided into two groups: one received pregabalin, and the other received placebo. The groups were matched for age, gender, and weight, and were followed for 14 weeks. At the end of the study, patients who had received pregabalin had a significant reduction in pain, compared to those who had received placebo. The patients who had received pregabalin also had a significant reduction in the number of days they had pain, compared to those who had received placebo.

The most common side effects were dizziness, sedation, blurred vision, weight gain, dry mouth, and swelling of the hands and feet. These side effects were generally mild and did not require discontinuation of treatment. The most common side effects were dizziness, sedation, blurred vision, weight gain, dry mouth, and swelling of the hands and feet. These side effects were generally mild and did not require discontinuation of treatment.

The daily dose should be administrated in two divided doses per day, starting at a total daily dose of 150 mg/day, which may be increased to 300 mg/day, within 1 week; the maximum dose is 300 mg/day, according to the prescribing information.

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