

FDA Approves First Drug for Treating Fibromyalgia

By Kristin Thorson
Posted: June 21, 2007

The FDA approved Lyrica (pregabalin) as the first drug with an indicated use for people with fibromyalgia syndrome (FMS). It was initially approved to treat neuropathic pain in January of 2005, but many physicians have been prescribing Lyrica "off-label" to treat their patients with FMS.

One year ago, pain specialist Jennifer Schneider, M.D., Ph.D., of Tucson, AZ, said, "These days I'm trying most of my FMS patients on Lyrica, and seeing highly variable results. Some complain that it makes them tired and dizzy, but others say it's a miracle! For this reason, I believe it is worth giving everyone a trial of Lyrica."

In the July 2006 Fibromyalgia Network Journal, we published interviews of three women who had amazing success with Lyrica. One stated, "Within days of starting Lyrica, I was able to forget I had FMS." Another person commented, "As far as energy levels go, WOW!!" However, Lyrica is not for everyone.

Drowsiness and dizziness are the most common side effects. For some patients, these effects may quickly dissipate in a few days, while they may force others to discontinue the drug. Blurred vision (9%), weight gain (10%), and fluid retention in the arms and legs, called peripheral edema (8%), may also occur with Lyrica. Counseling patients about the potential for weight gain may head off this side effect. As for the edema, it can force patients to stop the medication.

Talking about the peripheral edema side effect at the American Pain Society (APS) meeting on May 2nd, Leslie Crofford, M.D., of the University of Kentucky, says, "This is a difficult to manage symptom that does not respond to diuretics. When it occurs, I have to tell patients that this is not the drug for them."

A six-month blinded, placebo-controlled trial was presented by Crofford at the APS meeting to determine how long FMS patients maintained efficacy of the drug. Initially 1051 FMS patients were gradually dosed up on Lyrica during a six week period to determine who responded with a greater than 50% improvement in symptoms. Then the responders (566 patients) were divided into two groups. One group received the same dose of Lyrica that they had been taking for the past few weeks and the other group was placed on a placebo. None of the patients knew which group they were in.

Patients taking the placebo, after having a favorable response on Lyrica, quickly noticed an increase in symptoms. Two-thirds of the patients remaining on Lyrica continued to receive a good therapeutic response at the end of the six month trial. However, remember that only patients who demonstrated a favorable response to Lyrica (54%) were allowed into this six month trial.

In a separate study presented at the APS meeting, different doses were evaluated in 745 FMS patients. Doses of 300 mg to 450 mg/day were needed to reduce pain and improve function. Even at the lower dose of 300 mg/day, patients reaped significant benefits from improved sleep. If drowsiness side effects prohibit daytime use, Lyrica may still be beneficial if taken at night for sleep.

Lyrica is the first drug to be tested in several large-scale treatment trials in patients with FMS. Many more medications are being investigated for use in FMS and will hopefully be FDA-approved soon.