

FDA Approves Second Drug to Treat Fibromyalgia

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The U.S. Food and Drug Administration (FDA) approved Cymbalta (duloxetine) on June 16 for treating fibromyalgia. Cymbalta is the first serotonin-norepinephrine reuptake inhibitor (SNRI) that has been proven to reduce pain in fibromyalgia patients. This is the second FDA-approved medication to treat the disease, while the first was Lyrica (pregabalin) in June 2007.

The Fibromyalgia Network has been reporting on the progress of Cymbalta through clinical trials since the spring of 2004.

SNRI drugs, such as Cymbalta, are thought to relieve pain by increasing the availability of serotonin and norepinephrine (NE) in the central nervous system. These two neurotransmitters help filter out pain signals in the spinal cord so that fewer make it up to the brain. When serotonin and NE are released at the nerve endings, SNRIs latch onto these two neurotransmitters and carry them back across the nerve junction so that both can be reused to fight pain. In a way, SNRIs "recycle" the two neurotransmitters that are low in many patients with fibromyalgia.

In the most recent double-blind, randomized, phase III clinical trial of 520 men and women with fibromyalgia, researchers compared Cymbalta at 20 mg, 60 mg, and 120 mg doses taken once daily for six months versus placebo. People taking the two higher doses (but not 20 mg/day) reported pain reduction after the first week. After three and six months, patients taking either 60 or 120 mg daily reported a significant reduction in pain compared to patients taking the placebo. Aside from measures of pain, the two higher doses of Cymbalta also reduced mental fatigue, which might possibly relate to improvements in mental clarity.

Cymbalta was shown to be equally effective in men and women with and without mood disorders. Even people over 65 years of age reaped similar improvements in pain as those in the younger age groups.

Nausea, dry mouth, constipation, and sleepiness were the most common side effects of the medication. The side effects increased at the higher dose. Weight gain or blood pressure elevations may occur in a subgroup of patients taking Cymbalta.

Details on overcoming side effects, monitoring blood pressure and making adjustments for daytime sleepiness were reported in the January 2008 issue of the Fibromyalgia Network Journal. "The key message is to not give up too soon: try different doses and try taking it at different times during the day. Patients usually find the right approach for them," said Lesley Arnold, M.D. of the University of Cincinnati College of Medicine, in Ohio, and lead investigator for the clinical trials on Cymbalta.

Cymbalta has already been FDA-approved to treat diabetic peripheral neuropathic pain (DPNP), major depressive disorder, and generalized anxiety disorder, all in adults older than 18 years of age.

The FDA also added important warnings and precautions to the Cymbalta prescription information including who should not take this medication.

The July 2008 edition of the Fibromyalgia Network Journal outlines the progress of six additional medications that are currently being tested for the treatment of fibromyalgia.