NEWS FROM THE FDA

Agency Adds New Pain Indication for Duloxetine

BY JENNIE SMITH

The Food and Drug Administration has approved the antidepressant duloxetine for the management of chronic musculoskeletal pain in adults, the agency announced.

The approval marks the fifth of duloxetine's U.S. licensed indications to date and its third for treatment of pain. Duloxetine, marketed as Cymbalta, was first approved in 2004 to treat depression, and later the drug gained indications for generalized anxiety disorder, diabetic neuropathy, and fibromyalgia. All of the indications are for people aged 18 years and older. The drug has received European Union marketing authorization for depression, anxiety, and diabetic neuropathy only.

The mechanism by which duloxetine, a serotonin and norepinephrine reuptake inhibitor, works on pain is uncertain, Eli Lilly said in a press statement accompanying the announcement. However, it is believed to increase the availability of both neurotransmitters, enhancing the body's natural pain-suppressing system.

In August the FDA's Anesthetic and Life Support Drugs Advisory Committee had voted 8-6 to recommend the extension of indication for duloxetine, a vote that was considered too narrow to predict what the agency would ultimately decide. The drug's effectiveness was not well agreed upon, either, with an 8-5 vote in favor, and 1 member abstaining.

Evidence from two studies submitted to the agency by the manufacturer (n= 236 and n = 401) showed that duloxetine at oral doses of 60-120 mg daily reduced chronic lower back pain better than placebo after 12 and 13 weeks. Evidence from a third study (n = 404) showed no benefit. For osteoarthritis, one study (n = 256) showed a statistically significant reduction in pain after 13 weeks in people taking between 60 and 120 mg, and another study (n = 231) did not.

The maximum dosage for the musculoskeletal pain indication, which includes osteoarthritis and lower back pain, is 60 mg/day, the same as the maximum recommended dosage for depression. Adverse events included nausea, dry mouth, insomnia, sleepiness, constipation, dizziness, and fatigue.

Osteoarthritis affects 27 million American adults, the company said. About 70%-85% experience low back pain at some time, with some reports estimating that up to a tenth of these will go on to have chronic back pain. ■

Sodium Oxybate Nixed for Treatment of Fibromyalgia

BY ELIZABETH MECHCATIE

The Food and Drug Administration has decided that the sedative-hypnotic drug sodium oxybate cannot be approved for treatment of fibromyalgia, based on the information currently included in the approval application, the manufacturer has announced.

The statement issued by Jazz Pharmaceuticals noted that the FDA's "complete response letter" said the new drug application for sodium oxybate cannot be approved "in its present form" and cited the need for more clinical studies. The FDA's letter also discusses the proposed Risk Evaluation and Mitigation Strategy (REMS), as well as the concentration and trade name for sodium oxybate, according to Jazz. Other topics discussed in the letter include the need for methods to ensure safe use of the drug, the sodium salt of gamma hydroxybutyrate, an endogenous neurotransmitter synthesized from gamma aminobutyric acid, which is also known as the "date rape" drug for its potent sedative effects.

It is the FDA's practice to send complete response letters to sponsors of new drug applications when there are concerns about whether the drug should be approved and to outline information needed to complete the approval process. The agency does not comment on products under review, and therefore does not release information on these letters.

The concerns that the Jazz statement said were outlined in the letter reflect those expressed by members of two FDA advisory panels at a summer meeting held to review the data on sodium oxybate for the fibromyalgia indication. At the meeting, most of the panelists voted against recommending approval, citing the lack of long-term data and other concerns regarding the drug – including its potential for illicit use.

The drug's only approved indication is for the treatment of narcolepsy, a fairly uncommon condition. Were sodium oxybate to be approved for fibromyalgia, which is more common, it is possible that the drug would be more likely to be misused because it would be present in more family medicine cabinets.

Sodium oxybate also is the active ingredient in Xyrem, which is approved for treating excessive daytime sleepiness and cataplexy in adults with narcolepsy.

The Jazz statement says that the company has requested a meeting with the FDA to discuss the complete response letter, and will then evaluate the next steps for the drug. ■

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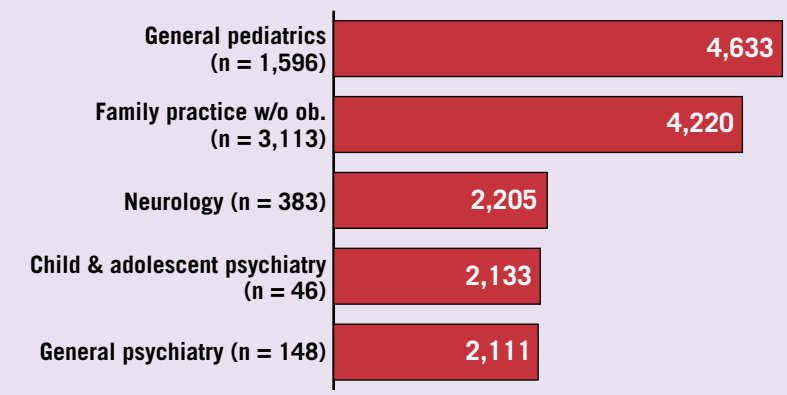

Note: Based on a 2009 survey of physicians in group practice.
Source: Medical Group Management Association

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