THERAPY

**SODIUM OXYBATE
FOR FIBROMYALGIA**

Building on evidence from earlier clinical trials, the results of a 14-week, phase III double-blind randomized trial demonstrate that the central nervous system depressant sodium oxybate (γ -hydroxybutyrate) is safe and effective for the treatment of fibromyalgia. The drug, which is currently approved for the treatment of narcolepsy symptoms, alleviated not only pain but also a number of other patient-reported outcomes of the disorder.

In the multicenter trial, 548 patients with fibromyalgia were randomly allocated to receive nightly doses of 4.5 mg or 6.0 mg sodium oxybate, or placebo. The primary endpoint, $\geq 30\%$ reduction in pain (as measured on a 100 mm visual analog scale [VAS]), was met by 54.2% and 58.5% of patients who received 4.5 mg and 6.0 mg sodium oxybate, respectively, compared with 35.2% of those who received placebo. These improvements in the sodium oxybate groups—which correspond to patients feeling “much better” or “very much better”—were observable as early as week 1, and were maintained throughout the 14-week study period.

Similarly, by week 1 the active treatment produced considerable improvements in fatigue VAS scores, which continued for the duration of the trial. Sodium oxybate treatment also improved subjective measures of sleep disturbance and patient-reported physical functioning at week 14, consistent with what is known about the drug's effects and the relationship between disturbed sleep and daytime symptoms in patients with fibromyalgia.

The overall incidence of treatment-related adverse effects, the most common of which was headache, was similar in the 4.5 mg and 6.0 mg sodium oxybate groups (46.7% and 48.4%, respectively), higher than reported in the placebo group.

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Original article Russell, I. J. *et al.* Sodium oxybate reduces pain, fatigue, and sleep disturbance and improves functionality in fibromyalgia: results from a 14-week, randomized, double-blind, placebo-controlled study. *Pain* doi:10.1016/j.pain.2010.12.022