

Xyrem seems to relieve pain in fibromyalgia

SAN DIEGO, April 3 (APM) – Orphan Medical/Jazz Pharmaceuticals/UCB's Xyrem (sodium oxybate) seems to relieve pain and improve sleep quality in patients with fibromyalgia, a study presented on Sunday at the annual meeting of the American Academy of Neurology (AAN) in San Diego suggests.

The study on sodium oxybate was presented in poster form at a special session on sleep disorders, the first scientific session of the AAN meeting which is expecting 10,000 attendees between now and next Saturday.

In this study financed by Orphan Medical, Todd Swick, the director of the Houston Sleep Center, evaluated sodium oxybate in 188 patients with fibromyalgia.

They stopped taking their fibromyalgia treatment three weeks before the beginning of the trial. During this period, pain symptoms were evaluated and patients were found to have a mean score of 65 points on a visual analogue scale (VAS) evaluating pain.

Patients were randomised in double-blind fashion between 4.5 g or 6 g sodium oxybate, administered at night, and placebo for two months. 147 patients completed the study.

The intention to treat results show that both doses of sodium oxybate significantly reduced pain compared to placebo – a reduction to 50 points (vs 58 points) on the VAS.

Sodium oxybate was also shown to be effective using the Fibromyalgia Impact Questionnaire (FIQ), which evaluates both pain and fatigue, with a decrease of about 20 points for the two doses of sodium oxybate, compared with a 10-point decrease for patients taking placebo.

Sodium oxybate's mechanism of action for pain is still badly understood, Dr Swick told APM.

Secondary evaluation criteria also suggests a benefit for sodium oxybate on quality of sleep, with an increase in slow sleep, notably phases 3 and 4 (deep sleep) and a significant decrease in the

percentage of rapid eye movement (REM) sleep compared to placebo.

The most frequent adverse effects with the two doses of sodium oxybate were nausea (15% at 4.5 g and 28.4% at 6 g, compared with 9.2%) and dizziness (respectively 6.7% and 13.4% vs 1.5%).

There was no open-label extension to this study, but 70% of participants asked to continue using sodium oxybate, Swick said.

These results suggest that sodium oxybate, administered at bedtime, improves sleep architecture, with beneficial effects on daytime symptoms in patients with fibromyalgia, the researchers conclude.

Asked about further studies, Swick said that another trial had begun on about 100 patients for a period of 14 to 16 weeks, with a combined primary endpoint linked to both pain and fatigue. Depending on the results, an indication extension application might be filed.

Sodium oxybate, developed by US company Orphan Medical, which was acquired by fellow American company Jazz Pharmaceuticals last year, has been marketed in the USA since 2002 in the treatment of excessive daytime somnolence and cataplexy in patients with narcolepsy.

In Europe, sodium oxybate was approved in October 2005 in the treatment of cataplexy in patients with narcolepsy. It was launched in December 2005 in Germany by Belgian group UCB, which acquired distribution rights for the European market.

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[2034] 03/04/2006 09:12 GMT – NEURO RHEUMATO