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COMPARISON OF SLEEP OUTCOMES IN GENERALIZED ANXIETY DISORDER FOLLOWING TREATMENT WITH PREGABALIN OR VENLAFAXINE-XR

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Objective: To evaluate the differential effect of pregabalin and venlafaxine-XR versus placebo on sleep outcomes in non-depressed outpatients with generalized anxiety disorder (GAD).

Methods: This secondary analysis was based on data from a double-blind trial in which adults who met DSM-IV criteria for GAD were randomized to 8-weeks of flexible-dose treatment with pregabalin (300-600 mg/d; N=121; baseline HAM-A=27.6), venlafaxine-XR (75-225 mg/d: N=125; HAM-A=27.4), or placebo (PBO; N=128; HAM-A=26.8). Sleep was evaluated at baseline, weeks 4, 8, and endpoint using the Medical Outcomes Study (MOS) Sleep Scale, including an overall sleep problems index (SPI), as well as sub-scale scores such as sleep disturbance.

Results: At baseline, 64% of patients with GAD met MOS-Sleep scale criteria for insomnia. Treatment with pregabalin was associated with significant endpoint improvement in the MOS-SPI compared to both placebo (-18.1 vs. -10.5; $P < 0.01$) and venlafaxine-XR (-10.1: $P < 0.01$). Treatment with pregabalin was associated with significant endpoint improvement in the MOS-sleep disturbance score compared to both placebo (-22.2 vs. -12.0; $P < 0.001$) and venlafaxine-XR (-11.6: $P < 0.001$). While somnolence as a treatment-emergent adverse event occurred more frequently on pregabalin (9.1%) compared to venlafaxine-XR (4.8%) and placebo (2.3%), overall, patients treated with pregabalin reported greater reduction in daytime sleepiness compared to venlafaxine-XR on the MOS-daytime sleepiness sub-scale (-9.7 vs. -5.8).

Conclusions: Treatment of moderate-to-severe GAD with pregabalin was associated with significantly better sleep outcomes compared to both placebo and venlafaxine-XR. Improvement in anxiety on pregabalin was associated with reduction in daytime sleepiness.