LONG-TERM EFFICACY AND SAFETY STUDY OF PREGABALIN IN SUBJECTS WITH GENERALISED ANXIETY DISORDER (GAD)

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Introduction: Pregabalin is indicated for the treatment of GAD in adults in Europe. The efficacy and safety of pregabalin for the treatment of adults and elderly patients with GAD has been demonstrated in 6 of 7 short-term clinical trials of 4 to 8 weeks.
Aims/objectives: To characterise the long-term efficacy and safety of pregabalin in subjects with GAD.
Methods: Subjects were randomised to double-blind treatment with either high-dose pregabalin (450-600 mg/d), low-dose pregabalin (150-300 mg/d), or lorazepam (3-4 mg/d) for 3 months. Treatment was extended with drug or blinded placebo for a further 3 months.
Results: At 3 months, mean change from baseline Hamilton Anxiety Rating Scale (HAM-A) for pregabalin high- and low-dose, and for lorazepam ranged from -16.0 to -17.4. Mean change from baseline Clinical Global Impression-Severity (CGI-S) scores ranged from -2.1 to -2.3 and mean CGI-Improvement (CGI-I) scores were 1.9 for each active treatment group. At 6 months, improvement was retained for all 3 active drug groups, even when switched to placebo. HAM-A and CGI-S change from baseline scores ranged from -14.9 to -19.0 and -2.0 to -2.5, respectively. Mean CGI-I scores ranged from 1.5 to 2.3. The most frequently reported adverse events were insomnia, fatigue, dizziness, headache, and somnolence.
Conclusions: Efficacy was observed at 3 months, with maintained improvement in anxiety symptoms over 6 months of treatment. These results are consistent with previously reported efficacy and safety trials of shorter duration with pregabalin and lorazepam in subjects with GAD.
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