A multicenter, placebo-controlled, double-blind study of efficacy of a new form of carbamazepine (Carbatrol®) in refractory epileptic patients

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Carbatrol (CBR) is a new multiple-unit, sustained-release dosage form of carbamazepine (CBZ) developed by Pharmavene. We present a multicenter, outpatient, randomized, double-blind parallel group study (No PI 101) carried out in two centers in Poland. CBR was evaluated in 47 patients with uncontrolled partial onset seizures. During the 28-day baseline period, patients were required to have at least two seizures and to take CBZ at a therapeutic level, a second antiepileptic drug was allowed but not valproic acid (VPA). Patients were randomized to VPA or to CBR (dosages 800, 1200, 1600 mg/day). Criteria for escape relative to baseline were: two-fold increase in monthly seizure frequency, two-fold increase in 2-day seizure frequency, two-fold increase in weekly seizure frequency, single generalized tonic-clonic seizure (GTCs) if none occurred during baseline or prolongation of GTCs. The primary efficacy variable was the number of patients escaping in each treatment group. Nineteen patients on VPA and 7 on CBR met escape criteria. CBR adverse experiences were all mild or moderate in severity. CBR therapy was effective in the treatment of partial complex seizures with or without generalization.

Key words: carbamazepine, carbatrol, uncontrolled partial seizures, epilepsy

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