Safety profile of eslicarbazepine acetate in eldery patients with focal onset seizures: from clinical studies to 8 years of post-marketing experience

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Objective: Evaluate the safety profile of eslicarbazepine acetate (ESL) in elderly patients diagnosed with focal seizures (FS) from clinical studies to 8-years of clinical experience. Material and methods: Data from double-blind and open-label phase II/III clinical studies in patients with FS (BIA-2093-201,-301(Part I–IV),-302(Part I-II),-303(Part I-II),-304(Part I),-311(Part I), and -401) were pooled and analyzed for elderly (≥65-years-old) and non-elderly (65-years-old) adult patients. Post-marketing safety data since first launch (1-Oct-2009) up to 21-Oct-2017 were obtained from safety reports received spontaneously, from health authority, literature, non-interventional studies, and other solicited sources as part of pharmacovigilance activities. Results: In clinical trials, at least one Treatment Emergent Adverse Event (TEAE) occurred in 82.5% (99/120) of elderly *vs.* 77.0% (1434/1863) non-elderly patients, with 51.7% reported as possibly-related TEAEs in elderly *vs.* 54.5% non-elderly. 20% of elderly patients discontinued treatment due to TEAEs *vs.* 16.9% non-elderly. Serious TEAEs were more common in elderly patients (22.5%) than in non-elderly (7.6%), with 6.7% and 2.5% assessed at least possibly-related, respectively. Most frequently reported TEAEs in elderly patients were dizziness (10.8% *vs.* 20.3% non-elderly), somnolence (9.2% *vs.* 12.6% non-elderly), hyponatremia (6.7% *vs.* 1.5% non-elderly), fatigue (5.8% *vs.* 3.5% non-elderly), and headache (5.8% *vs.* 8.3% non-elderly). After 8-years of post-marketing experience, 473 and 2406 Adverse Drug Reactions (ADRs) were reported for elderly and non-elderly patients, respectively. Most frequent reported ADRs (elderly *vs.* non-elderly) were hyponatremia (14.6% *vs.* 6.8%), drug dose titration not performed (7.0% *vs*. 5.4%), product use in unapproved indication (4.9% *vs*. 1.9%), and off-label use (3.4 *vs.* 2.2%); followed by dizziness (3.4% *vs*. 3.5%), fatigue (1.3% *vs*. 1.9%) and somnolence (1.0% *vs*.1.8). Conclusions: The qualitative safety profile of ESL in elderly patients after 8-years of clinical experience is consistent with data obtained from clinical studies.

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