

Alopecia in Association with Lamotrigine Use; An Analysis of Individual Case Safety Reports in a Global Database

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Abstract

Background: The WHO Programme for International Drug Monitoring, maintained by the Uppsala Monitoring Centre (UMC), has more than 90 member countries contributing individual case safety reports (ICSRs) from their existing national pharmacovigilance systems; these reports are stored in the WHO global ICSR database, VigiBase. A continuous increase of ICSRs of alopecia in suspected connection to lamotrigine use has been observed in VigiBase; however, only limited information has been published on this topic.

Objective: To examine in greater detail the association between lamotrigine and alopecia by outlining the characteristics of the accumulated reports in VigiBase.

Method: An analysis of all reports in VigiBase, up to 1 April 2009, where lamotrigine was suspected of having caused alopecia.

Results: Lamotrigine was suspected of being involved in the development of alopecia in 337 patients, reported from 19 countries. The age of the patients ranged between 5 months and 84 years (mean 36 years), with a predominance (58%) of patients <40 years of age. 272 patients were female. In 291 reports, lamotrigine was the only drug suspected by the reporter, and in 112 reports, lamotrigine was the sole reported drug. Commonly co-reported drugs were other antiepileptic drugs. For 217 patients, alopecia was reported as the single event. In 11 patients, the reaction abated on cessation of lamotrigine. One patient was reported to have had a recurrence of alopecia on re-administration of lamotrigine.

Conclusions: The UMC continues to receive reports of alopecia associated with the use of lamotrigine. Although alopecia may not be regarded as serious from a regulatory perspective, this adverse reaction has the potential to affect compliance, resulting in decreased efficacy of the treatment regimen and detrimental effects on patient health outcomes.

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