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## Interchangeability of generic anti-epileptic drugs: a quantitative analysis of topiramate and gabapentin.

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### Abstract

**PURPOSE:** The objective of this study was to determine whether the so-called "shift" or "drift" problem might occur when generic anti-epileptic drugs are interchanged, and thus to assess if generic anti-epileptic drugs are interchangeable and can be used in an efficacious and safe way on the basis of their bioequivalence to one and the same reference product.

**METHODS:** The bioequivalence of **topiramate** and **gabapentin** generics was evaluated. For proper interstudy comparison, individual exposure data (AUC and C(max)) for each bioequivalence study present in the registration dossier was normalized based on the absolute exposure data of one of two innovators. The exposure-normalized plasma concentration curves of the generic product arms between studies were compared, providing indirect evidence of bioequivalence of the different generics. Additionally, comparisons were made for generic-generic as well as innovator-innovator exchange based on absolute exposure data from individual bioequivalence studies.

**RESULTS:** In almost all cases, estimated 90% confidence intervals of the AUC and C(max) ratios for generic-generic interchange were within the routine 80-125% criterion. When absolute, non-corrected exposure data were used for this interstudy comparison, in a number of cases 90% confidence intervals outside the 80-125% criterion were found upon interchanging generics from two studies. However, a similar pattern of 90% confidence intervals outside the 80-125% criterion was observed for the comparison of innovator arms, despite the fact that the innovator was identical in all studies.

**CONCLUSION:** Our results strongly indicate that the so-called drifting problem upon generic-generic substitution does not result in important differences in exposure upon exchanging **topiramate** generics or **gabapentin** generics.

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### MeSH Terms, Substances

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