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Suicidality and Antiepileptic Drugs

FDA ALERT [1/31/2008] - The FDA has analyzed reports of suicidality (suicidal behavior or ideation) from placebo-controlled clinical studies of eleven drugs used to treat epilepsy as well as psychiatric disorders, and other conditions. These drugs are commonly referred to as antiepileptic drugs (see the list below). In the FDA's analysis, patients receiving antiepileptic drugs had approximately twice the risk of suicidal behavior or ideation (0.43%) compared to patients receiving placebo (0.22%). The increased risk of suicidal behavior and suicidal ideation was observed as early as one week after starting the antiepileptic drug and continued through 24 weeks. The results were generally consistent among the eleven drugs. Patients who were treated for epilepsy, psychiatric disorders, and other conditions were all at increased risk for suicidality when compared to placebo, and there did not appear to be a specific demographic subgroup of patients to which the increased risk could be attributed. The relative risk for suicidality was higher in the patients with epilepsy compared to patients who were given one of the drugs in the class for psychiatric or other conditions.

All patients who are currently taking or starting on any antiepileptic drug should be closely monitored for notable changes in behavior that could indicate the emergence or worsening of suicidal thoughts or behavior or depression.

This information reflects FDA's current analysis of available data concerning these drugs. Posting this information does not mean that FDA has concluded there is a causal relationship between the drug products and the emerging safety issue. Nor does it mean that FDA is advising health care professionals to discontinue prescribing these products. FDA intends to update this document when additional information or analyses become available.

- **Healthcare Professional Information**
 - [Information for Healthcare Professionals](#)
- **Other Information**
 - [FDA News: FDA Alerts Health Care Providers to Risk of Suicidal Thoughts and Behavior with Antiepileptic Medications](#)

The following is a list of antiepileptic drugs* included in the analyses:

Labeling and approval history from Drugs@FDA.

- [Carbamazepine](#) (marketed as Carbatrol, Equetro, Tegretol, Tegretol XR)
- Felbamate (marketed as Felbatol)
- [Gabapentin](#) (marketed as Neurontin)
- [Lamotrigine](#) (marketed as Lamictal)
- [Levetiracetam](#) (marketed as Keppra)

- [Patient Information Sheet](#)
- [Oxcarbazepine](#) (marketed as Trileptal)
- [Pregabalin](#) (marketed as Lyrica)
- [Tiagabine](#) (marketed as Gabitril)
- [Topiramate](#) (marketed as Topamax)
- [Valproate](#) (marketed as Depakote, Depakote ER, Depakene, Depacon)
- [Zonisamide](#) (marketed as Zonegran)

* Some of these drugs are also available in generic form.

[↑ Back to Top](#) [↖ Back to Drug Information](#)

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