



FDA News

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FDA Alerts Health Care Providers to Risk of Suicidal Thoughts and Behavior with Antiepileptic Medications

The U.S. Food and Drug Administration today issued new information to health care professionals to alert them about an increased risk of suicidal thoughts and behaviors (suicidality) in patients who take drugs called antiepileptics to treat epilepsy, bipolar disorder, migraine headaches, and other conditions.

An FDA analysis of suicidality reports from placebo-controlled studies of 11 antiepileptic drugs shows that patients taking these drugs have about twice the risk of suicidal thoughts and behaviors (0.43 percent), compared with patients receiving placebo (0.22 percent). This risk corresponds to an estimated 2.1 per 1,000 more patients in the drug treatment groups who experienced suicidality than in the placebo groups.

"We want health care professionals to have the most up to date drug safety information," said Russell Katz, M.D., director of the Division of Neurology Products in FDA's Center for Drug Evaluation and Research. "This is an example of FDA working with drug manufacturers throughout products' lifecycles to keep health care professionals informed of new safety data."

Patients who are currently taking antiepileptic medicines should not make any changes without first talking to their health care provider. Health care providers should notify patients, their families, and caregivers of the potential for an increase in the risk of suicidal thoughts or behaviors so that patients may be closely observed for notable changes in behavior.

Following a preliminary analysis of data from several antiepileptic drugs that suggested an increased risk of suicidality, in March 2005 FDA requested this type of data from manufacturers of marketed antiepileptic drugs for which there were adequately designed controlled clinical trials. FDA received and reviewed data from 199 placebo-controlled studies of 11 drugs.

The analysis included 27,863 patients in drug treatment groups and 16,029 patients in placebo groups. There were four suicides among patients in the drug treatment groups and none among patients in placebo groups. There were 105 reports of suicidal thoughts or behaviors in the drug-treated patients and 35 reports in placebo-treated patients.

The higher risk of suicidal thoughts and behaviors was observed at one week after starting a drug and continued to at least 24 weeks. The results were generally consistent among all the different drug products studied and were seen in all demographic subgroups. There was no clear pattern of risk across age groups.

Antiepileptic drugs in the analyses included the following:

Carbamazepine (marketed as Carbatrol, Equetro, Tegretol, Tegretol XR)
Felbamate (marketed as Felbatol)
Gabapentin (marketed as Neurontin)
Lamotrigine (marketed as Lamictal)
Levetiracetam (marketed as Keppra)
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.

Although only the drugs listed above were part of the analysis, the FDA expects that all medications in the antiepileptic class share the increased risk of suicidality.

FDA will be working with manufacturers of marketed antiepileptic drugs to include this new information in the labeling for these products. The agency anticipates that labeling changes will be applied broadly to the entire class of drugs. FDA is also planning to discuss these data at an upcoming advisory committee meeting.

For more information

FDA Information for Healthcare Professionals: Suicidality and Antiepileptic Drugs
www.fda.gov/cder/drug/InfoSheets/HCP/antiepilepticsHCP.htm.

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