

SPINE SAFETY WARNING:

Information for Healthcare Professionals: Antiepileptic Drugs- FDA Analysis Showed Patients Receiving Antiepileptic Drugs Had Approximately Twice The Risk of Suicidal Behavior Or Ideation

According to MedWatch, FDA informed healthcare professionals that the Agency 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. 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. The relative risk for suicidality was higher in patients with epilepsy compared to patients who were given one of the drugs in the class for psychiatric or other conditions.

Healthcare professionals should closely monitor all patients currently taking or starting any antiepileptic drug for notable changes in behavior that could indicate the emergence or worsening of suicidal thoughts or behavior or depression.

The drugs included in the analyses include (some of these drugs are also available in generic form):

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)

Although the 11 drugs listed above were the ones included in the analysis, FDA expects that the increased risk of suicidality is shared by all antiepileptic drugs and anticipates that the class labeling changes will be applied broadly.

Read the complete 2008 MedWatch Safety Summary including a link to the Healthcare Professional Sheet regarding this issue at:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#Antiepileptic>

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS website at <http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.