



Breakthrough Seizures and Mylan Generic Drug Lawsuits

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CONTENTS

About Epilepsy	2
Epilepsy Medications: Anti-Epileptic Drugs, AEDs, Anticonvulsant Drugs, Generics	3
Epilepsy Drugs: Generic vs. Brand	4
Generic Keppra Side Effects, LVT for Epilepsy	5
FAQ: Lawsuits, Epilepsy Resources, Generic Lamictal, Unsafe Generic AEDs	6
Resources	7

DISCLAIMER: This information is not intended to replace the advice of a doctor. Please use this information to help in your conversation with your doctor. This is general background information and should not be followed as medical advice. Please consult your doctor regarding all medical questions and for all medical treatment.



ABOUT EPILEPSY

Epilepsy refers to a tendency to have recurrent seizures. A seizure is a temporary disturbance in brain function affecting mental and physical functions. During a seizure, disturbances of nerve cell activity produce symptoms that vary depending on which part and how much of the brain is affected. Seizures lasting a few seconds to a few minutes may produce changes in awareness and other changes in behavior lasting much longer than the actual seizure. Seizures have different symptoms from convulsions and loss of consciousness to blank staring, lip smacking, or jerking movements of arms and legs.



One in ten adults will have a seizure during his or her lifetime.

Epilepsy may arise when there are disruptions to the normal connections between nerve cells in the brain. Some disruptions and changes may develop early in life or be hereditary factors and relate to early exposure. Others may be acquired later. Here are some possible causes of epilepsy:

- Oxygen deprivation during childbirth
- Brain infections such as meningitis, encephalitis
- Traumatic brain injury or head injury
- Stroke resulting from a ruptured blood vessel in the brain
- Other neurologic diseases like Alzheimer disease
- Brain tumors
- Certain genetic disorders

However, in almost two-thirds of epilepsy cases, the underlying cause is not identified.

Following the emergence of the [Mylan generic epilepsy drug](#) on the market, complaints-from consumers, consumer watchdog groups, and the medical community-came pouring in, not only to the Food & Drug Administration but to numerous consumer and special interest groups. Patients whose seizures had been effectively controlled for months if not years were experiencing seizures shortly after being switched to the Mylan generic [epilepsy drug](#). Such events are referred to as breakthrough seizures. Breakthrough seizures can be particularly devastating to individuals whose epilepsy had been successfully treated for years.

EPILEPSY MEDICATIONS: Anti-Epileptic Drugs, AEDs, Anticonvulsant Drugs, Generics

Anti epileptic drugs don't cure epilepsy.

Unfortunately, modern medicine has accomplished a lot but not enough because currently there is no cure for epilepsy.

AEDs help prevent further seizures. Some people will see a significant reduction in the number of seizures they have. Some people will not have any seizures for long periods of time. And some will not need medication and can remain seizure free. Sadly, even people who take AEDs will continue to have seizures despite medication.

First generation or early anti epileptic drugs included bromide, Phenobarbital, Dilantin, Tridione, Valium, Tegretol, and Depakene.

Beginning in 1993, a new class of AEDs emerged and came to be known as second-generation AEDs. The newer AEDs have different pharmacokinetic profiles and mechanisms of action when compared to the first-generation AEDs. Second generation AEDs are better tolerated with less serious side effects and safer than older first generation AEDs. Second generation AEDs include Levetiracetam (LVT) under the Keppra brand, felbamate (Felbatrol), gabapentin (Neurontin), lamotrigine (Lamictal), topiramate (Topamax),

tiagabine (Gabitril), oxcarbazepine (Trileptal), pregabalin (Lyrica), and zonisamide (Zonegran).

Anticonvulsants are a class of drugs indicated for the treatment of various types of seizures associated with epilepsy and other disorders. Anticonvulsants are often effective in controlling seizures associated with epilepsy. Some anticonvulsants and AEDs are used in psychiatry for the treatment of manic depression.





EPILEPSY DRUGS: Generic vs. Brand

Neurologists who treat patients with epilepsy have patient safety concerns.

Two studies published in the journal *Neurology* found that patients who switched from a brand-name product to a generic one had more seizures or higher hospitalization rates.

When taking a seizure medication, the therapeutic window for error or dosage is narrow. If the epilepsy's drug absorption is slightly different between brand and generic or between generics, then the patient could have a seizure, and that seizure could lead to serious injury or perhaps even death.

According to the Food & Drug Administration, generic drugs are required to have the same active ingredient, strength, dosage form, and route of administration as the brand name. Generic drugs do not need to contain the same inactive ingredients as the brand product.

In November 2009, the American Academy of Neurology (AAN), which represents over 19,000 neurologists and neuroscience professional, issued a position statement on the coverage of anticonvulsant drugs for the treatment of epilepsy. Their position is: The AAN opposes generic substitution of anticonvulsant drugs for the treatment of epilepsy without the attending physician's approval.

With everything being status quo, patients may suffer serious epileptic consequences without knowing why while taking generic AEDs. The second-generation anti seizure drugs such as [generic versions of Keppra](#) (Levetiracetam or LVT) and Lamictal (lamotrigine) have generated numerous complaints and much frantic discussion in online epilepsy forums.

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The problem is not only in changing from a name-brand epilepsy drug to a generic epilepsy drug, but also in switching from generic to generic epilepsy drugs.

Unfortunately, patients may be unaware that the change is even happening.

When patients are on maintenance medication for which a generic is available, they might be given a different version of the generic drug when refilling their prescriptions. A pharmacy might stock one generic for a few months, and then switch to another a few months later, if the store is offered a better deal. A pharmacist is not required to notify patients regarding the change of generic epilepsy drugs.



GENERIC KEPPRA SIDE EFFECTS, LVT FOR EPILEPSY

Breakthrough seizures can be particularly devastating to people whose epilepsy had been successfully treated for years. Just one breakthrough can have serious implications both socially such as revocation of driver's license and employment problems, and personally, such as loss of confidence, risk of injury, and effect on family members.

Post-generic breakthrough seizures and/or the onset of adverse events have clinical implications as well, given the time and cost to re-establish seizure control, as well as costs associated with injury and/or hospitalization. Additionally, many patients reported that the generic Keppra was causing them to experience adverse [side effects](#) for the first time.

Nationwide, doctors who were unaware of the differences between the Keppra the brand and generic Keppra, responded by increasing the dosage resulting in more adverse side effects for their patients.

Patients who lived seizure-free lives with minimal side effects on brand name Keppra suffered contrasting night and day experiences on generic Keppra. Problems associated with the generic Keppra include:

- Dizzy spells
- Prolonged light-headedness
- Muscle spasms
- Migraine headaches
- Loss of coordination
- Shortness of breath
- Light sensitivity
- Long-term headaches
- Blood sugar drop
- Low blood pressure
- Aggression
- Nausea
- Hair loss
- Depression

Generic Keppra has problems from the company who makes it, [Mylan Inc.](#), to the pharmacy who negligently fills the prescription without notifying the doctor or patient.



FAQ: Lawsuits, Epilepsy Resources, Generic Lamictal, Unsafe Generic AEDs

Can I afford a Mylan generic Keppra lawsuit?

The answer is yes. If you agree to hire [Anapol Schwartz law firm](#) and Anapol Schwartz law firm agrees to be hired, you both sign an agreement stating so. Anapol Schwartz represents [unsafe drug lawsuits](#) on a contingency fee basis. This means if you do not win your case, Anapol Schwartz does not get paid. Anapol Schwartz has offices in Philadelphia, Reading, Media, and Harrisburg, Pennsylvania; Cherry Hill, New Jersey; and Wheeling, West Virginia.

Is epilepsy fatal?

Most people with epilepsy live a full life span. However, the risk of premature death is increased by being fatally injured during a seizure; sometimes epilepsy is a symptom for a more seriously underlying condition like stroke or tumor which carries an increased risk of death; and a series of prolonged seizures in rapid succession can also be life threatening.

Are there problems with generic lamotrigine?

Yes, most of the MedWatch adverse events involved a loss of response, but many involved a loss of response and additional side effects that did not occur with the brand-name Lamictal. According to a clinical nurse specialist who filed 37 MedWatch reports, she believes the generic equivalents of Lamictal differ markedly in bioequivalence, enough so that they may actually cause harm to patients. She also worries that the problems with generics AEDs are more pervasive than being reported.

Where can I learn more about epilepsy?

Try the [Epilepsy Foundation](#) or the [Charlie Foundation](#) for pediatric epilepsy.



If anti-epileptic drugs don't work, are there other options?

Yes, for some there is surgery and for children, dietary therapy known as the ketogenic diet. According to Wikipedia, the ketogenic diet is a high-fat, adequate-protein, low-carbohydrate diet primarily used to treat difficult-to-control epilepsy in children. The diet mimics aspects of starvation by forcing the body to burn fats rather than carbohydrates. Normally, the carbohydrates contained in food are converted into glucose, which is then transported around the body and is particularly important in fuelling brain function. However, if there are very little carbohydrates in the diet, the liver converts fat into fatty acids and ketone bodies. The ketone bodies pass into the brain and replace glucose as an energy source. An elevated level of ketone bodies in the blood, a state known as ketosis (like the Atkins diet), leads to a reduction in the frequency of epileptic seizures.

What kind of questions should I be asking a potential unsafe generic drug law firm?

You have questions; Anapol Schwartz has the answers. It is perfectly acceptable to ask a law firm about their experience, settlements, procedures, and costs. We listen to your concerns and outline the process. With over 30 attorneys, many leaders in their field, Anapol Schwartz is devoted to unsafe drugs like Mylan generic Keppra, product negligence, medical malpractice, and [personal injury lawsuits](#) in Pa., NJ, and WVa.

RESOURCES

www.anapolschwartz.com

www.fda.gov

www.epilepsyfoundation.com

www.charliefoundation.com

