

# ercurrent

Monthly newsletter from the **epilepsy** RESOURCE CONNECTION

## FDA Issues Carbamazepine Warning

The Food and Drug Administration (FDA) recently issued a warning about the use of carbamazepine (Carbatrol, Equetro, Tegretol, Tegretol XR and generic formulations) in patients who have a very specific type of an HLA gene. Patients with HLA-B\*1502 (an inherited variant of the HLA-B gene) are at substantially increased risk of developing serious, potentially life threatening skin reactions called toxic epidermal necrolysis and Stevens-Johnson syndrome, characterized by multiple skin lesions, blisters, fever, itching and other symptoms, compared to people without this gene.

The HLA-B\*1502 gene is found almost exclusively in patients with Asian ancestry. While it appears that patients with ancestry from many parts of Asia, including South Asian Indians may have an increased chance of having this gene, the exact frequency for various specific ethnic groups is still somewhat unclear. It is believed that as many as 10-15% of patients from China, Taiwan, Thailand, the Philippines, Malaysia and Indonesia may test positive for this gene. Japanese and Korean patients may have a lower frequency, less than 1%, of carrying this gene.

Until more is known, the FDA is advising that patients of Asian descent, including those of mixed ancestry, undergo a blood test prior to starting carbamazepine treatment. Testing for HLA-B\*1502 is a commonly performed blood test in patients prior to having organ transplants, in order to determine tissue compatibility. It is important to recognize that testing positive for this gene is not abnormal, and there are no other known medical risks associated with having it other than an increased risk of serious rash from carbamazepine.

Those patients who test positive for the specific type of HLA gene should discuss with their doctor whether the possible benefits outweigh the risks and whether there are any other options besides carbamazepine. In addition, although it is not clear what (if any) additional risks there might be, FDA is suggesting that physicians may want to avoid starting treatment with any antiepileptic drugs that have been associated with Stevens Johnson Syndrome as well.

It is also important for patients to know that the vast majority of patients who do develop a serious skin rash, will do so within the first few months of treatment. So patients (including those testing positive for HLA-B\*1502), who have been taking carbamazepine for more than several months are at very low risk of developing these serious rashes. ⇄ [EPILEPSY.COM](http://EPILEPSY.COM)



## Adult Epilepsy Support Group

**Meets Second Tuesday of Month,  
5:00 PM @ 2919 W. 2nd Street, Wichita**

February 12th: "Stress Management"  
March 11th: "Recognizing Seizure Triggers"



**NEW START TIME of 5:00 PM** will allow for Wichita Transit bus service to and from the group!!! The West Central bus passes in front of our building on 2nd Street.



## Our New "Current" Look

Welcome to our new look. We have launched our newly redesigned newsletter and we hope that you find the new name and format an experience more enjoyable. That's what changed, the rest is the same—we will continue to bring you the most current informative articles about epilepsy and its effects.

### DRUG WATCH

## Acute Repetitive Seizures Drug Gets FDA's "Go Ahead"

Jazz Pharmaceuticals, Inc. has received orphan drug designation from the FDA for its JZP-8 drug for the treatment of recurrent acute repetitive seizures. In December 2007, Jazz Pharmaceuticals dosed the first patient in a Phase II clinical trial of JZP-8.

JZP-8 is a novel drug delivery formulation incorporating clonazepam, a widely prescribed benzodiazepine. The product candidate is designed to be a fast-acting intranasal spray for the treatment of recurrent acute repetitive seizures in patients with epilepsy. Jazz Pharmaceuticals previously completed development activities to select the active pharmaceutical ingredient for the product, to determine its formulation, and to assess its safety and tolerability in early stage studies.

Recurrent acute recurrent repetitive seizures (ARS) are bouts of acute seizure activity occurring within a 24-hour period in adults and a 12-hour period in children. ARS, also called seizure clusters, occurs in a small subset of patients with epilepsy who regularly experience breakthrough seizures in flurries or clusters despite treatment with a regimen of anti-epileptic drugs. ARS is a rare disorder, with an estimated prevalence in the United States of approximately 90,000 to 180,000 people.

Orphan drug designation is granted by the FDA to encourage the development of treatments for diseases or conditions that affect fewer than 200,000 patients in the United States. Drug products that receive orphan drug designation obtain seven years of marketing exclusivity from the date of FDA marketing approval, as well as tax credits for clinical trial costs and waivers of marketing application filing fees.

Jazz Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on identifying, developing and commercializing innovative products to meet unmet medical needs in neurology and psychiatry. ⇄ [MEDICAL NEWS TODAY](http://MEDICALNEWS.TODAY)

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## Treating With Atkins-Like Diet: Leptin Lessens Mice Seizure Severity

Not all individuals who have epilepsy respond to traditional treatments and these individuals are said to have medically refractory epilepsy. Strict use of a ketogenic diet high in fats and extremely low in carbohydrates is sometimes used for treatment of refractory epilepsy, and is effective about half of the time. However, the mechanisms whereby ketogenic diets suppress epileptic symptoms have long been a mystery. New data generated by Kelvin Yamada and colleagues at the Washington University School of Medicine, St. Louis, has revealed that intranasal delivery of leptin, a hormone important in feeding and energy metabolism, delayed the onset of convulsions in a rodent model of seizures. As indicated by Tamas Horvath and Sabrina Diano in an accompanying commentary, these data suggest that leptin-triggered signaling may be a key to how a ketogenic diet combats epilepsy.

In the study, when focal seizures were induced by injection of the chemical 4AP into rat brains, co-injection of leptin reduced both the length and the frequency of these seizures. Intranasal administration permitted leptin to cross the blood-brain barrier and delay the onset of chemical-induced generalized seizures in mice. Additional experiments revealed that leptin may assert these antiseizure effects via interaction with the JAK2/PI3K signaling pathway. The authors concluded that successful epilepsy treatments may include dietary changes to increase leptin levels, intranasal administration of the compound, and pharmacological targeting of JAK2/PI3K signaling pathways.

✦ MEDICAL NEWS TODAY

*Editor's Note: This information is provided for your reference only. You should never begin an epilepsy treatment regimen without consulting your physician.*

## Teva Approved For Oxcarbazepine

Teva Pharmaceutical Industries Ltd., an Israeli company, has announced that the FDA has granted final approval for the company's Abbreviated New Drug Application (ANDA) to market its generic version of Novartis' antiepileptic therapy Trileptal® (Oxcarbazepine) Tablets, 150 mg, 300 mg and 600 mg. Shipment of the product will begin in the near future.

The brand product had annual sales of approximately \$690 million in the United States in 2007.

In October 2007 the FDA approved the first generic versions of Trileptal (oxcarbazepine). Currently, three manufacturers market oxcarbazepine. The approved manufacturers are Sun Pharmaceutical Industries (Caraco), Glenmark Pharmaceuticals and Roxane Laboratories. The Sun and Glenmark products are made in India. ✦ MNT



### NOTEWORTHY

If you are taking Trileptal®, Novartis has a value card that may help you receive the drug at a discount. For more info visit: [www.trileptal.com](http://www.trileptal.com)

The Arc of Sedgwick County  
2919 West Second Street  
Wichita, Kansas 67203

erc, JobForce & Office This present

## ↑ WORK SUCCESS ↓

A Free Employment Workshop for Persons with Epilepsy

January 25, 2007

9:00 a.m. - Noon

@ Office This (4031 E. Harry)

Join the Employment Specialists from JobForce Employment Solutions® for this FREE hands-on workshop. \*Participants will explore opportunities and strategies to overcome employment barriers to persons with epilepsy. TO ATTEND, please REGISTER by calling (316) 943-1191 or on-line at [www.epilepsybrainstorms.org](http://www.epilepsybrainstorms.org)



## Winter fun 'n Games

Sat. Feb 2, 2007

9:30 a.m. - 12:00 Noon

@ ERC (2919 W. 2nd Street)



Fun, lunch and connect with other families facing similar challenges of living with a seizure disorder. Includes free lunch (donations are accepted to help defray costs.) Pull the kids away from the cartoons... And join other families affected by epilepsy for a morning of indoor fun for all ages! We will have Inflatables for the kids to bounce in. Adults will enjoy a challenging game of Cranium!! If you haven't played it, imagine combining charades and a trivia game. Everyone can contribute giving their team a moment to shine.



To attend, please register at (316) 943-2453