

Important New Option For Children With Epilepsy

(NAPSA)—There's encouraging news for the half million children with epilepsy and their families. For the first time in 25 years, the U.S. Food and Drug Administration (FDA) approved an antiepileptic drug, Trileptal® (oxcarbazepine), as monotherapy (use alone, without the aid of one or more other antiepileptic medications) for treatment in children with partial seizures four years of age and older. Partial seizures are a common kind of seizure that occur most frequently in one area of the brain. Many children with epilepsy take multiple medications to control their seizures; however, treating epilepsy with one medication is preferred as it usually means fewer side effects and makes it easier for patients to follow prescribed treatment schedules.

"The approval of Trileptal as pediatric monotherapy is a step forward in the treatment of childhood epilepsy," said Tracy Glauser, M.D., Associate Professor of Pediatrics and Neurology, Director of the Comprehensive Epilepsy Program, Cincinnati Children's Hospital Medical Center and Trileptal clinical trial investigator. "Trileptal has been used as monotherapy in adults. Now this use can be extended to children four years of age and older."

Epilepsy, often referred to as a seizure disorder, is a condition that is associated with recurrent electrical discharges in the brain that disrupt the functioning of the nervous system. The bursts of electrical energy that result may cause seizures, which can affect



Important news for families living with epilepsy.

consciousness, bodily movements or sensations. Most seizures last under two minutes; however, some forms can last for a longer period of time and, in some cases, can be fatal.

In the United States, more than 500,000 children 18 years of age and younger have epilepsy and more than three million adults and children live with the condition. On average, children with seizure disorders tend to be one year behind their peers in reading abilities. Compared to their peers, these children are more likely to repeat grades and drop out of school. Compounding the situation is that seizures can cause mental confusion and memory loss that may impair a child's ability to concentrate in the classroom, study and/or complete homework assignments.

Trileptal first received marketing clearance in the United States in January 2000 and is approved in more than 60 countries. For safety and other information please visit www.Trileptal.com.

Note to Editors: As monotherapy and as adjunctive therapy in pediatric patients, adverse events with Trileptal were similar to adults. The most common side effects (occurring in at least 5% of patients treated with Trileptal in clinical studies and substantially more frequently than in placebo patients) were dizziness, sleepiness, double vision, fatigue, nausea, vomiting, incoordination, abnormal vision, abdominal pain, tremor, indigestion, and abnormal gait—these were typically mild to moderate in severity.

Use of Trileptal is not generally associated with cosmetic side effects or weight gain. In addition, no hepatic, hematologic or drug-level monitoring is required. Patients should avoid driving or operating machinery until they determine how Trileptal affects these activities.

A condition called hyponatremia (low blood sodium levels) has been observed in some patients treated with Trileptal. Measurement of serum sodium levels should be considered for patients at risk of hyponatremia. (Please see Warnings section of complete prescribing information.)

Patients should inform their doctors if they have used the drug carbamazepine in the past. Twenty-five percent to 30% of patients who have had allergic reactions to carbamazepine will experience allergic reactions to oxcarbazepine. (Please see Warnings section of complete prescribing information.)

Use of Trileptal with birth control pills may render birth control pills less effective. Additional forms of contraceptives are recommended when using Trileptal.

For more information, please see complete prescribing information at www.Trileptal.com.