

# Vigabatrin for adjunctive therapy for the treatment of refractory complex partial seizures in adults

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*A nonprofit 501-c-3 organization*

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- Formed by parents of children living with uncontrolled seizures together with their doctor.
- Our Mission:  
To advance new therapies for people living with epilepsy

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REMINDER: OR-Live.com Presents: Neurosurgeon to Perform Epilepsy Surg During Live Internet Broadcast

March 1, 2006  
March is Epilepsy Awareness Month in Canada - Lavender. Think of Epilepsy

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Does Treatment Aggressiveness Affect the Prognosis of Refractory Status Epilepticus?

### UPCOMING EVENTS

### EPILEPSY NEWS

Mar 24, 2006  
SCN1A-associated epilepsy is linked to a channel dysfunction

Mar 24, 2006  
Depression treatment in coronary artery disease trial is announced

Mar 24, 2006  
Clinical depression may be associated with higher risk of out-of-hospital cardiac arrest

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### FEATURE ARTICLES



Epilepsy affects  
more than 50  
million people  
worldwide  
including 3  
million in the US



## EPILEPSY FACTS

- 30% live with seizures uncontrolled by existing therapies.
- Another 2/3 face side-effects from their medicines as a price of seizure control .
- Their families share the burden of epilepsy.

# What it means to have uncontrolled seizures

- Despite the availability of more than a dozen medications to treat partial-onset seizures, there is no “magic bullet” that is effective and tolerable for everyone.
- Every new medication is useful for patients. Some prefer sz control while others prefer lack of adverse effects.
  - The choices are not simple, but people deserve the opportunity to choose what is best for them.

# Vigabatrin Efficacy and Tolerability

- In early studies of >2000 adults, the most common side effects were drowsiness (12.5%) and fatigue (9%)
  - Also seen were adverse effects typical among antiepileptic drugs: irritability/nervousness, dizziness, headache, depression, weight gain
- Later assessments showed that ~ ~25% of patients taking vigabatrin long-term developed visual field deficits.

# FREEDOM OF (INFORMED) CHOICE

- Mr. Smith had uncontrolled partial-onset seizures.
  - After trying every available medication and many combinations, he became seizure-free on a combination of valproate, vigabatrin and lamotrigine.
  - With this success, he regained an independent life, was married, and began to drive.
- After 2 years, he was informed that VGB was associated with visual field deficits in some people.
  - On examination, he was shown his own visual field restriction (40%) as mapped out by a neuro-ophthalmologist.

# LESSONS

1. VGB was effective after other medications had not controlled his sz.
2. Epilepsy had a devastating social burden when his sz were not controlled. He was unable to work or live independently. His life reversed with the optimum medication combination, found after many trials.
3. The doctor considered him an autonomous agent who has the right to determine what to do or to accept as treatment options.  
After careful consideration, he chose to continue taking VGB

- “In discussing this issue with the patient, we could not guarantee that he would remain seizure-free if we stopped vigabatrin or that an alternative treatment regimen would be as effective.
- Furthermore, we could not provide confirmation that stopping vigabatrin would reverse the deficit, nor could we advise that maintenance of vigabatrin would result in further deterioration.”

– Roy Beran, MD, Sydney, NSW, Australia, epileptologist and President of the Australian College of Legal Medicine.

# Patient's rights to make decisions

- “The decision to continue with vigabatrin was not made lightly and was an informed consent by both (the patient and his wife).” R. Beran
- **We urge FDA to give patients a choice.**
  - CNS example:
    - Clozapine: weekly WBC tests required before 7-day refill dispensed





Epilepsy Therapy Project  
supports approval of:  
*Vigabatrin for adjunctive therapy for the  
treatment of refractory complex partial  
seizures in adults*