



In Support Of NDA 20-427: Vigabatrin Adjunctive Therapy of Refractory Complex Partial Seizures in Adults

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Outline

- American Epilepsy Society
- Urgent need for new therapies for adults with refractory complex partial seizures
- Clinical decision-making: Individualizing the risks and benefits
- Vigabatrin
- My personal experience
- Summary

American Epilepsy Society-est. 1936

- Promotes research and education for professionals dedicated to the prevention, treatment and cure of epilepsy
- The annual meeting of the American Epilepsy Society is the premiere conference for exchange of information about the diagnosis and treatment of epilepsy

American Epilepsy Society-est. 1936

- Members are epileptologists (neurologists who specialize in epilepsy), neurosurgeons, nurses, neuropsychologists, pharmacologists, neuroscientists, allied health professionals
- Close relationships with other professional organizations including American Academy of Neurology, Child Neurology Society and International League Against Epilepsy

Urgent Need for New Therapies for Refractory CPS

- Despite available antiepileptic drugs, a large proportion of patients with epilepsy still have seizures
- Complex partial seizures are particularly resistant to available antiepileptic drugs and are the most common seizure type in adults
- Possible complications of refractory complex partial seizures include death and life-altering injuries
- **Therefore there is an urgent need for new therapies for refractory complex partial seizures**

Clinical Decision Making: Individualizing the Risks and Benefits

- Epilepsy clinicians choose antiepileptic drugs based on their individualized assessment of risks and benefits
 - ◆ Possible risks of the drug to an individual patient and the possible consequences
 - ◆ Potential benefit to an individual patient and the potential impact on quality of life

Clinical Decision Making: Individualizing the Risks and Benefits

- The risk-benefit assessment is individualized for each patient based on available information, clinical experience and training, and detailed knowledge of the individual patient's circumstances
- Epilepsy clinicians make these assessments every day for FDA-approved AEDs and surgical interventions with possible life-threatening or life-altering side effects or complications

Vigabatrin

- There is an urgent need for new therapies for refractory complex partial seizures
- Vigabatrin represents an important new treatment option
 - ◆ Published clinical trial data support its use in adults with refractory complex partial seizures
 - ◆ Potential side effects are well-described
 - ◆ Substantial use in clinical practice outside of US to inform the risk-benefit assessment
 - ◆ Unique mechanism of action

My Personal Experience

- I have cared for thousands of patients with epilepsy over the past 25 years
- I have personally seen the devastating effects of refractory complex partial seizures on adult patients and their families
- I have personally witnessed the remarkable turnaround in the lives of my adult patients when their complex partial seizures came under control

Summary

- The prevalence and complications of refractory complex partial seizures in adults are substantial: we therefore urgently need new therapies
- Epilepsy clinicians base their treatment decisions on applying the risks and benefits to individual patients
- The American Epilepsy Society educates prescribers about the diagnosis of epilepsy and the risks and benefits of treatments

Summary

- Vigabatrin represents an important new treatment option for adults with refractory complex partial seizures
- ***Thank you*** for your careful consideration of all these factors

***“How do you adequately thank
someone for giving you back
control of your life?”***