



In Support Of NDA 22-006: Vigabatrin Treatment of Infantile Spasms

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January 8, 2009

American Epilepsy Society-est. 1936

- Promotes research and education for professionals dedicated to the prevention, treatment and cure of epilepsy, including infantile spasms
- AES members include pediatric epileptologists - pediatric neurologists who specialize in epilepsy
- AES has close relationships with other professional organizations including the Child Neurology Society, American Academy of Neurology, and International League Against Epilepsy

New Therapies for Infantile Spasms are Urgently Needed

- West syndrome is a severe epilepsy syndrome, associated with poor prognosis and significant morbidity and mortality
- No approved Rx; all current treatments are off label
- Effective therapy improves developmental outcome; benefits last a lifetime
- There remains a significant and urgent need for new therapies for infantile spasms

Vigabatrin

- Vigabatrin is an important new treatment option
- Published clinical trial data support its use for infantile spasms, esp. when associated with tuberous sclerosis
- Potential side effects are well described
- Substantial use in clinical practice outside of US to inform the risk-benefit assessment and the clinical approach to starting and stopping vigabatrin in patients with infantile spasms

Choosing Seizure Treatments (AEDs): Individualizing the Risks and Benefits

- Epilepsy clinicians choose AEDs by assessing the risks and benefits for individual patients based on available information about AEDs, clinical experience and training, and detailed knowledge of the individual patient's neurological and medical condition
- 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

Summary

- New therapies for infantile spasms are urgently needed
- Vigabatrin is an important new treatment option
- Epilepsy clinicians individualize treatment decisions by applying the risks and benefits to individual patients
- The American Epilepsy Society educates prescribers about the diagnosis of infantile spasms and the risks and benefits of treatments
- ***Thank you*** for your careful consideration of these factors