Keppra® Fact Sheet

- Keppra® (levetiracetam) tablets, an anti-epileptic drug (AED), was first approved by the U.S. Food and Drug Administration (FDA) in 1999 as adjunctive therapy in the treatment of partial onset seizures in adults with epilepsy. In June 2005, Keppra® was approved by the FDA as adjunctive therapy in the treatment of partial-onset seizures in children 4 years of age and older with epilepsy. Since its launch, Keppra® has had more than 600,000 unique patient starts in the United States¹ and is the most prescribed second generation AED used in epilepsy.²

- Keppra® is available in 250, 500 and 750 mg tablets and a grape-flavored (100 mg/mL) oral solution for patients who prefer a liquid or have difficulty swallowing tablets. Taken with or without food, the recommended starting dose of Keppra® in adults is 1,000 mg/day given twice daily (500 mg bid). For children (4 to < 16 years of age) the recommended starting dose is 20 mg/kg/day (10 mg/kg bid). Keppra® dosing must be individualized according to renal function status.

- Keppra® offers effective seizure control with no clinically significant drug interactions. Keppra®’s limited metabolism is not dependent on any liver cytochrome P450 isoenzymes. It is excreted primarily by the kidneys and circulates largely unbound to plasma proteins.

- Keppra® is supported by an extensive research and development program, exploring the potential benefits of Keppra® in a broad range of diseases that affect the central nervous system.

- UCB Pharma CNS scientists have recently identified the binding site for levetiracetam in the brain as a synaptic vesicle protein called SV2A. This protein appears to have an important, although not completely defined, role in the release of neurotransmitters that are essential for normal neuronal activity in the brain and spinal cord.³ The precise mechanism of action for Keppra® has not been fully established.

- The identification of the binding site for Keppra® provides an innovative and unique drug discovery platform to identify new drugs with improved characteristics at UCB Pharma and further confirms that Keppra® possesses a mechanism of action distinct from that of other AEDs.³ No other known anti-epileptic drugs bind to SV2A. The clinical significance of these findings is unknown.

- Developed by the global research-based pharmaceutical sector of UCB S.A., with worldwide headquarters in Brussels, Belgium, Keppra® is marketed in the United States by Georgia-based UCB Pharma, Inc.

Information about adult clinical trials with Keppra®

- In adult phase III clinical trials, Keppra® demonstrated significant reduction in seizure frequency in a difficult-to-treat, highly refractory patient population experiencing partial onset seizures with or without secondary generalization.

- Low discontinuation or dose reduction rates due to an adverse event – Keppra® was 15 percent vs. 11.6 percent for placebo.

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In adults, Keppra® (levetiracetam) use is associated with the occurrence of central nervous system adverse events, including somnolence and fatigue, coordination difficulties, behavioral abnormalities, as well as hematological abnormalities.

In well-controlled adult clinical studies, the most frequently reported adverse events associated with the use of Keppra® in combination with other AEDs, not seen at an equivalent frequency among placebo-treated patients, were somnolence, asthenia, infection and dizziness.

Retrospective analysis of data from four prospective clinical studies concluded that treatment with Keppra® is not associated with significant weight change, and that Keppra® appears to be a weight neutral AED.

Information about pediatric clinical trials with Keppra®

Results from a multi-center, randomized double-blind, placebo-controlled trial demonstrated that in children, age 4 to 16 with partial seizures uncontrolled by standard antiepileptic drugs, adjunctive treatment with Keppra® resulted in 26.8 percent fewer seizures each week over placebo, on average.

In the same study, responder rates (the portion of patients achieving a 50% or greater reduction in seizures) for patients taking Keppra® were 44.6% versus 19.6% for placebo (p=0.0002 when compared to placebo).

In pediatric patients, 4 to 16 years of age, the most common adverse events associated with Keppra® in combination with other AEDs were somnolence, accidental injury, hostility, nervousness and asthenia. In pediatric patients, Keppra® is associated with somnolence, fatigue, and behavioral abnormalities, as well as hematological abnormalities.

Epilepsy

Epilepsy is a chronic disorder causing recurrent seizures, affecting more than 2.5 million Americans regardless of race, age or sex. Worldwide, epilepsy is one of the most common neurological disorders, and can strike at any time during one’s life. Epileptic seizures are classified into two main types: partial and generalized seizures.

Keppra® is indicated as adjunctive therapy in the treatment of partial onset seizures in adults and children 4 years of age and older with epilepsy.

Up to 80 percent of people with epilepsy can gain full or partial control of their seizures with treatments such as anti-epileptic drugs. Surgery, the ketogenic diet or an implanted device that delivers electrical stimulation to the brain are other treatment options.


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1 NDCHealth Retail Pharmacy Database, May 2000 – April 2005
2 IMS NDTI Drug Use, Rolling Quarter February – April 2005
3 Lynch BA, Lambeng N, Nocka K et al. The synaptic vesicle protein SV2A is the binding site for the antiepileptic drug levetiracetam. *PNAS* 2004;101(26): 9861-9866.
5 Glauser TA, Gauer LJ, Chen L and LEV N159 Pediatric Study Group. Multicenter, double-blind, placebo-controlled trial of adjunctive levetiracetam (Keppra®) therapy (up to 60 mg/kg/day) in pediatric patients with refractory partial epilepsy. Epilepsia 2004; 45 (supplement 7): 186

Please call or email contacts to obtain further information or copies of references.