

First generic version of epilepsy drug sabril approved

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(HealthDay)—The first generic version of Sabril (vigabatrin) has been approved by the U.S. Food and Drug Administration to prevent complex partial seizures in adults and children 10 and older with epilepsy.

"The availability of high-quality generic alternatives of critically important medicines, once the period of patent protection or exclusivity has ended on the brand drug, helps advance access and saves consumers billions of dollars each year," said FDA Commissioner Dr. Scott Gottlieb.

A complex partial seizure originates in a certain area of the brain, typically lasting 30 seconds to 90 seconds. Disorientation, confusion, fatigue and even loss of consciousness may follow, the FDA said in a news release.

The agency repeated prior assertions that generic equivalents are held to the same vigorous manufacturing standards as <u>brand-name drugs</u>, and have been deemed equally safe, effective and chemically equivalent.

Vigabatrin's label includes a boxed warning of the possibility of permanent vision loss. The drug's most common side effects include dizziness, fatigue, insomnia, involuntary eye movement, blurred vision, memory impairment and weight gain. A more serious adverse reaction may be suicidal thoughts or actions, the FDA said.

Approval of generic vigabatrin tablets was granted to Teva



Pharmaceuticals USA, whose parent company is based in Israel.

More information: The FDA has more about this approval.

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