AMERICAN HEALTH CARE

DRUG PRODUCTS & SAFETY NEWS

FDA Approves Sabril

June 22, 2016

Sabril (vigabatrin), an anticonvulsant medication, was approved on August 21, 2009 for use as monotherapy in infants one month to two years of age who suffer from infantile spasms, a form of epilepsy. Infantile spasms are associated with a poor prognosis that includes neurodevelopmental regression and a significant mortality rate. Sabril is also approved for use in combination with other medications for refractory partial complex seizures in patients 10 years of age and older who have responded inadequately to several alternative treatments.
Sabril was approved with a risk evaluation and mitigation strategy (REMS) to ensure that the benefits of Sabril outweigh the risks of vision loss and of suicidal thoughts and behaviors. Sabril can cause permanent bilateral concentric visual field constriction, including tunnel vision that can result in disability. In some cases, it also can damage the central retina and may decrease visual acuity. Since approval, the REMS has required periodic visual monitoring results to be documented through submission of ophthalmologic assessment forms (OAFs).
On June 21, 2016, the FDA announced the approval of a supplemental New Drug Application (sNDA) modifying the REMS for Sabril. The FDA determined that, although the risk of vision loss with Sabril still exists, the REMS should be modified to remove certain elements.

Healthcare professionals and patients are encouraged to report any adverse events or side effects related to the use of this product and/or quality problems to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- ✓Complete and submit the report online: www.fda.gov/MedWatch/report.htm
- ✓Complete and return a form by mail (address on the pre-addressed form) or fax (1-800-FDA-0178).

[Call 1-800-332-1088 to request a reporting form or download a form at http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm.]

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http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm507990.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

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