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IN BRIEF

Ezogabine (Potiga) Toxicity

The FDA recently announced changes in the labeling of ezogabine (*Potiga* – GSK/Valeant) to warn about the risks of retinal abnormalities, possible vision loss, and bluish skin discoloration, all of which could be permanent.¹

Ezogabine was approved in 2011 for adjunctive treatment of partial-onset seizures in adults.² The FDA first warned about these risks in April 2013.³ At that time, skin discoloration had developed in 38 of an estimated 605 patients (6.3%) who had taken the drug (most for \geq 2 years) in various studies. Retinal pigment abnormalities were found in 11 of 36 patients who had eye examinations; some of these patients had impaired visual acuity, but baseline visual acuity assessments were not available.

The new label recommends limiting the use of ezogabine to patients who have not responded adequately to several alternative antiepileptic drugs. Patients taking the drug should have a baseline eye exam and follow-up exams every 6 months.

- FDA Drug Safety Communication: FDA approves label changes for anti-seizure drug Potiga (ezogabine) describing risk of retinal abnormalities, potential vision loss, and skin discoloration. Available at www.fda.gov/Drugs/DrugSafety/ ucm372774.htm. Accessed November 18, 2013.
- Ezogabine (Potiga) for epilepsy. Med Lett Drugs Ther 2012; 54:65.
- FDA Drug Safety Communication: Anti-seizure drug Potiga (ezogabine) linked to retinal abnormalities and blue skin discoloration. Available at www.fda.gov/Drugs/DrugSafety/ ucm349538.htm. Accessed November 18, 2013.

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