Potiga (Ezogabine): Drug Safety Communication - Linked To Retinal Abnormalities And Blue Skin Discoloration

UPDATED 11/01/2013: FDA approved changes to the drug label, underscoring risks of abnormalities to the retina in the eye, potential vision loss, and skin discoloration, all of which may become permanent. The revised label includes a new boxed warning, because of the risk of abnormalities to the retina. FDA advises that Potiga use be limited to patients who have not responded adequately to several alternative therapies to decrease the frequency of seizures, or epilepsy, and for whom the benefits of treatment outweigh the risks.

AUDIENCE: Health Professional, Neurology, Patient

ISSUE: FDA is warning the public that the anti-seizure medication Potiga (Ezogabine) can cause blue skin discoloration and eye abnormalities characterized by pigment changes in the retina. FDA does not currently know if these changes are reversible. FDA is working with the manufacturer to gather and evaluate all available information to better understand these events. FDA will update the public when more information is available.

BACKGROUND: Potiga is approved as adjunctive (added on to other anti-seizure medications) treatment of partial-onset seizures in adult patients 18 years and older. Pigment changes in the retina have the potential to cause serious eye disease with loss of vision. It is not yet known whether the retinal pigment changes caused by Potiga lead to visual impairment, although several patients have been reported to have impaired visual acuity. In some cases, retinal abnormalities have been observed in the absence of skin discoloration. The skin discoloration in the reported cases appeared as blue pigmentation, predominantly on or around the lips or in the nail beds of the fingers or toes, but more widespread involvement of the face and legs has also been reported. Scleral and conjunctival discoloration, on the white of the eye and inside eyelids, has been observed as well. The skin discoloration generally occurred after four years of treatment with Potiga, but has appeared sooner in some patients.

RECOMMENDATION: In light of this new safety information all patients taking Potiga should have a baseline eye exam and periodic eye exams that should include visual acuity testing and dilated fundus photography, and may include fluorescein

angiograms (FA), ocular coherence tomography (OCT), perimetry, and electroretinograms (ERG). Potiga should be discontinued if ophthalmic changes are observed unless no other treatment options are available. If a patient develops skin discoloration, serious consideration should be given to changing to an alternate medication. Patients who are taking Potiga and develop any changes in their vision or any discoloration of their skin, including of their lips and nail beds, should contact their health care professional right away.

Patients should not stop taking Potiga without talking to their health care professional. Stopping such treatment suddenly can cause serious and life-threatening medical problems such as recurrence of seizures.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety

Information and Adverse Event Reporting Program:

- Complete and submit the report Online: **www.fda.gov/MedWatch/report.htm (https://web.archive.org/web/20170406124206/http://www.fda.gov/MedWatch/report.htm)**
- **Download form (/web/20170406124206/https://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm)** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[10/31/2013 - **Drug Safety Communication (/web/20170406124206/https://www.fda.gov/Drugs/DrugSafety/ucm372774.htm)** - FDA
[04/26/2013 - **FDA Safety Communication (/web/20170406124206/https://www.fda.gov/Drugs/DrugSafety/ucm349538.htm)** - FDA]

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2016 Safety Alerts for Human Medical Products (/web/20170406124206/https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm479348.htm)

2015 Safety Alerts for Human Medical Products (/web/20170406124206/https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm428326.htm)

2014 Safety Alerts for Human Medical Products (/web/20170406124206/https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm380008.htm)

2013 Safety Alerts for Human Medical Products (/web/20170406124206/https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm333878.htm)