

GlaxoSmithKline

PO Box 13398

Five Moore Drive

Research Triangle Park

North Carolina 27709-3398

Tel. 919 483 2100

www.gsk.com

IMPORTANT PRESCRIBING INFORMATION

Date: August 2016

Subject: POTIGA® (ezogabine) Tablets, CV, 50mg, 200mg, 300mg, 400mg—Discontinuation of Commercial Availability

Dear Healthcare Professional:

GlaxoSmithKline (GSK) is advising healthcare providers that POTIGA (ezogabine) Tablets, CV, 50mg, 200mg, 300mg and 400mg will no longer be commercially available after June 30, 2017.

GSK intends to permanently discontinue the product due to the very limited usage of the medicine and the continued decline in new patient initiation. Discontinuation is not due to efficacy or safety reasons.

POTIGA® is a potassium channel opener indicated as adjunctive treatment of partial-onset seizures in patients aged 18 years and older who have responded inadequately to several alternative treatments and for whom the benefits outweigh the risk of retinal abnormalities and potential decline in visual acuity.

Action required by Health Care Providers

Healthcare providers are advised to begin seeking alternative medicines for existing patients as soon as possible and to ensure all patients are withdrawn from POTIGA by the end of June 2017 at the latest. Healthcare providers should not initiate any new patients on POTIGA during this approximately one-year transition period.

Patients should be gradually withdrawn from POTIGA over a period of at least 3 weeks. All patients should continue to receive safety monitoring while they remain on treatment with POTIGA. In order to monitor for retinal pigmentary abnormalities and potential vision loss, patients should have baseline ophthalmologic testing by an ophthalmic professional and follow-up testing every 6 months. The ophthalmologic monitoring program should include visual acuity testing, dilated fundus photography, and optical coherence tomography. Additional testing may include fluorescein angiograms, perimetry, and electroretinograms. Please refer to the Full Prescribing Information, including Boxed Warning, and Medication Guide that accompany this letter.

Action Being Taken by GlaxoSmithKline

GSK is communicating this information to the Food and Drug Administration (FDA) and healthcare providers. We are working closely with our distributors to ensure the drug remains available to existing patients for the next year, so there is sufficient time for a satisfactory treatment alternative to be identified and initiated.

Reporting Adverse Events

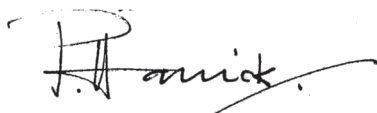
If you become aware of an adverse event involving POTIGA please contact:

- GlaxoSmithKline at 1-888-825-5249 and/or
- FDA MedWatch program by phone at 1-800-FDA-1088 or online at www.fda.gov/medwatch/report.htm

You may also contact our Medical Information department at 1-888-825-5249 if you have any questions about the medical information contained in this letter or the safe and effective use of POTIGA.

This letter is not a comprehensive description of the risks with the use of POTIGA. Please read the accompanying Full Prescribing Information, including Boxed Warning, and Medication Guide for a full description of these risks.

Sincerely,



Philip Hornick, MD, PhD
Vice President, Therapy Area Head, of Specialty, Classic and Established Products
US Medical Affairs



POTIGA is a registered trademark of Valeant Pharmaceuticals North America LLC.