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IMPORTANT MEDICINE SAFETY INFORMATION

BUPROPION CONTAINING MEDICINES - RISK OF BRUGADA SYNDROME

08 June 2023

Dear Healthcare Professional,

GSK South Africa, in collaboration with the South African Health Products Regulatory Authority (SAHPRA), would like to draw your attention to the following important safety information associated with bupropion-containing medicines, registered in South Africa.

Background on safety concern

- The safety concern is regarding the risk of Brugada syndrome associated with the use of bupropion-containing medicines. This safety issue was based on the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) Assessment Report for bupropion.
- In view of available data on Brugada syndrome from spontaneous reports, including two cases with a positive de-challenge and plausible time to onset and plausible mechanism of action described in literature, PRAC considered that bupropion may unmask Brugada syndrome.
- Brugada syndrome is generally an inherited, rare, arrhythmic disorder characterized by cardiac conduction abnormalities (ST segment abnormalities in leads V1-V3 on Electrocardiogram (ECG) and a high risk for ventricular arrhythmias) that can result in sudden death. [i]

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Advice to Healthcare professionals

- Symptoms of Brugada syndrome range from absence of any symptoms to sudden cardiac death that typically occurs during sleep, possibly secondary to increased vagal tone. Brugada syndrome is associated with ventricular tachycardia or ventricular fibrillation, syncope, palpitations and dizziness.
- Although Brugada syndrome is uncommon, its association with sudden cardiac death, due to ventricular fibrillation, requires that healthcare professionals be made aware of this side effect, its ECG presentation and modulating factors that may underlie a Brugada pattern, and be able to recognize, identify and promptly take corrective measures.
- Physicians need to be cautious when treating patients with a family history of cardiac arrest or sudden death.
- The patient, family and colleagues need to be educated about the syndrome, its potential for cardiac arrest and about basic cardiopulmonary resuscitation (CPR), after diagnosis.
- Healthcare professionals are urged to report any adverse drug reactions (ADRs) or product quality issues (including batch details) via Med Safety App. The App can be downloaded on a smart mobile phone through Google Play or App Store.
- Alternatively, healthcare professionals may report ADRs via the e-Reporting link available on the SAHPRA website (www.sahpra.org.za).
- Additionally, reporting can be done via the ADR reporting form accessible via the SAHPRA website and email it to adr@sahpra.org.za.

For more information on ADR reporting of products listed below, please contact the SAHPRA vigilance unit at pvqueries@sahpra.org.za, or alternatively use the contact details indicated below:

Table 1: Company Products

Company	Product name	Active ingredient	Registration Number	Contact details
GlaxoSmithKline (Pty) Ltd Nicol Main Office Park, 2 Bruton Road, Block A, Bryanston, 2191	Voxra XL 150	Bupropion Hydrochloride	41/1.2/0373	Email: Aereporting.za@gsk.com Tel: +27 10 300 1000
	Voxra XL 300	Bupropion Hydrochloride	41/1.2/0374	
	Wellbutrin XL 150	Bupropion Hydrochloride	41/1.2/0371	
	Wellbutrin XL 300	Bupropion Hydrochloride	41/1.2/0372	

Yours faithfully,

Dr Santoshni Govindasamy Country Medical Director, GSK South Africa

Reference

Brugada R, Campuzano O, Sarquella-Brugada G, et al. Brugada Syndrome. 2005 Mar 31 [Updated 2022 Aug 25]. In: Adam MP, Mirzaa GM, Pagon RA, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2023. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1517/