FOOD AND DRUGS AUTHORITY
FDA
GHANA
Your Well-being, Our Priority

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12th May 2023

Dear Healthcare Professional,

STRENGTHENED RISK MANAGEMENT FOR SODIUM VALPROATE AND MANDATED CHANGES TO THE PRODUCT INFORMATION

Further to the previous communication in 2019 on the Valproate Pregnancy Prevention Programme (PPP) the Food and Drugs Authority (FDA) writes to remind healthcare professionals about adherence to the programme and inform you about additional precautions regarding reduced fertility in males exposed to sodium valproate.

The update is based on recommendations from the FDA's Technical Advisory Committee on Safety of Medicines following a review of the updated statement by the Commission on Human Medicines, United Kingdom regarding use of sodium valproate.[1]

Healthcare professionals are to take note of the underlisted when prescribing sodium valproate.

- Sodium valproate should not be prescribed to female children or women of childbearing potential unless other treatments are ineffective or not tolerated. Any use of valproate in women of childbearing potential, who cannot be treated with other medicines, should be in accordance with the Pregnancy Prevention Programme.

- All other suitable therapeutic options should be considered before prescribing sodium valproate for the first time in male or female patients younger than 55 years.

- Prescription of sodium valproate in male patients should be done with caution as there is the potential risk of impaired fertility. This effect on male fertility is, however, reversible upon discontinuation or reduction in the dose of the valproate.

- Persons on sodium valproate treatment should undergo periodic review by a specialist e.g. paediatrician, physician or gynaecologist.

Sodium valproate is registered by the FDA for the treatment of generalized, partial or other epileptic seizures and marketed in Ghana as Epilim tablets and syrup. Babies exposed in utero to sodium valproate are at high risk of serious developmental disorders (in up to 30-40% of cases) and/or congenital malformations (in approximately 10% of cases).

[1] https://www.gov.uk/drug-safety-update/valproate-reminder-of-current-pregnancy-prevention-programme-requirements-information-on-new-safety-measures-to-be-introduced-in-the-coming-months

The FDA advises patients and healthcare professionals to report adverse reactions to sodium valproate and all other regulated products, including **lack of therapeutic effect**, **medication errors, suspected substandard or falsified products,** through the following:

- Download and complete the Med Safety App (Google Play Store or App Store)
- Complete and submit the report online at http://adr.fdaghana.gov.gh/patient.php;
- Call Mobile No. 024 4310 297
- Call Hot line No. 0308250070
- Download and complete the Adverse Reaction Reporting (ADR) Form, then submit it at the nearest healthcare facility

Yours faithfully,

SETH K. SEANEKE (MR.)
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FOR: CHIEF EXECUTIVE OFFICER