SAHPRA
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

Media Release

MEDICINES SAFETY COMMUNICATION

NEW MEASURES TO MINIMISE THE RISK OF VALPROATE USE IN PREGNANCY

To all Consumers and Healthcare Professionals

From: The Acting CEO of SAHPRA

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The South African Health Products Regulatory Authority (SAHPRA), in collaboration with manufacturers of sodium valproate (Epilim, Epilizine, Navalpro, Eprolep, Adco Sodium Valproate, Valeptic, Sandoz Sodium Valproate, Cerepiv and Convulex), hereby informs you of the new implemented measures aimed at reducing the risk of sodium valproate use in pregnancy.

Valproate-containing medicines are anticonvulsant medicines used to treat epilepsy and also used as a mood stabiliser in the treatment of bipolar mood disorder.

Valproate is associated with a very high risk of birth defects and developmental disorders in children born to women who take valproate during pregnancy. An estimated 10 % of babies (1 in ten) exposed to valproate during pregnancy are likely to develop a serious physical birth defect such as:

- spina bifida (spine and spinal cord does not develop properly),
- facial and skull malformations such as cleft lip/palate (upper lip or facial bones are not joined as one), and
- heart, kidney and limb defects.

In addition, about 30-40 % (3 or 4 out of 10) of children whose mothers took valproate while pregnant could develop long term developmental problems such as:

- walking or talking late
- learning disabilities and lower intelligence compared to other children of the same age
- poor speech and language skills
- memory problems
- increased likelihood of having autism and autistic spectrum disorder
- a higher risk to develop symptoms of attention deficit hyperactivity disorder (ADHD)

SAHPRA reminds consumers and health care professionals (HCPs) of these risks. For this reason, the Authority and valproate manufacturers have implemented new measures which aim to ensure that:

- girls and women of child-bearing potential are not started on valproate treatment unless no other effective treatment is available, and
- girls and women already on valproate treatment are made well aware of the risks of using valproate during pregnancy and the need to take adequate measures to avoid falling pregnant while on valproate.

The new measures implemented include:

- Updating the professional information and patient information leaflet to highlight the risks and to ban the use of valproate during pregnancy unless there is no other effective treatment available.
- Including educational materials aimed at avoiding the use of valproate in female children and women of child-bearing potential.
- A new Acknowledgement of Risk Form which will need to be signed by the patient or guardian indicating that they are aware of the risks and the need to avoid becoming pregnant in cases where valproate use in girls and women of child-bearing potential is unavoidable. An additional form needs to be signed by the doctor who verifies that they have informed the patient of the risks.
- In cases where the use of valproate is unavoidable or where it is the only medicine that works, contraception must be used continuously in women and girls who are able to become pregnant and must be discussed with the doctor.
- Girls and women of child-bearing potential who are currently taking valproate should go back to their doctor to review the need for this treatment, the option to switch to another treatment and to assess the effectiveness of contraception.
- The requirement of annual monitoring of women and girls who are using valproate.

Note: Consumers are advised not to abruptly stop taking valproate particularly during pregnancy, as this can cause seizures which may be harmful to an unborn baby. A doctor must be consulted without delay if a woman or girl who is taking valproate suspects she is pregnant. The doctor will decide on how, when and which medicine to switch to.

Healthcare professionals are urged to review the product information including the new educational materials provided by companies to ensure that they are aware of the risks and communicate these risks with patients, providing them with the patient information leaflet, patient card and other educational materials.

Healthcare professionals and consumers in South Africa are also urged to report any adverse reactions to the National Adverse Drug Event Monitoring Centre at (021) 4471618 SAHPRA pharmacovigilance office on (012) 395 9133/8197/8155 or using the reporting form which can be accessed at https://www.sahpra.org.za/documents/86422f1b6.04_ARF1_Jul16_v4.pdf

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