Western Cape Government

Department of Health & Wellness
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TO: DDG: CHIEF OF OPERATIONS / CHIEF DIRECTORS / DIRECTORS
HEADS OF INSTITUTIONS
MANAGER: CAPE MEDICAL DEPOT
HEAD OF HEALTH: CITY OF CAPE TOWN
RESPONSIBLE PHARMACIST: CHRONIC DISPENSING UNIT

N.B. FOR CIRCULATION TO ALL MEDICAL, PARAMEDICAL, PHARMACEUTICAL AND NURSING PERSONNEL

VALPROATE ANNUAL RISK ACKNOWLEDGEMENT FORM

Dear Colleagues

This circular is to be read in conjunction with Circulars H52-2019 and H17-2020.

In accordance with the attached South African Health Products Regulatory Authority (SAHPRA) media release dated 30th November 2018, it is a legal requirement for all girls and women of childbearing age (potential) who are on valproate, or their guardian, to sign an annual Valproate Acknowledgment of Risk Form. An additional form must be signed annually by the prescriber who verifies that they have informed the patient of the risks. Both forms must be kept in the patient's folder.

Pharmacists must endorse referral prescriptions that the consent forms were signed by both the patient and prescribers as well as the date of the signatures. It is also recommended that where possible, pharmacists should make a note on JAC/Wellsky on the patient/ dispensing profile that the patient and prescriber have signed the forms as well as the date of the signatures.

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Please refer to the attached forms which may be used in the Western Cape Government: Health & Wellness.

Patient Guides for women of childbearing potential receiving valproate referred to in the forms will be distributed to facilities by the Cape Medical Depot with orders for valproate during July/August 2023.

Your co-operation is appreciated.

Klowenherz

MS K. LOWENHERZ
DIRECTOR: MEDICINE MANAGEMENT, LABORATORY AND BLOOD SERVICES SUPPORT
WESTERN CAPE GOVERNMENT: HEALTH AND WELLNESS
DATE: 25/07/23

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Valproate Annual Risk Acknowledgement Form for patient or guardian

VALPROATE HAS A RISK IN PREGNANCY

Date of consent:	
Next date when consent due:	

If you use valproate while you are pregnant, your child has significant risk of serious harm. This form confirms that you or your caregiver/parent/responsible person understand the risks of using valproate.

Part A: To be completed and signed by the valproate user and/or caregiver/parent or responsible person.	
I have discussed the following with the specialist/doctor, and I understand:	
Why I need valproate rather than another medicine;	☐ Yes
That I should visit a doctor regularly (at least once a year) to review whether valproate remains the best option for me.	☐ Yes
The risks in children whose mothers took valproate during pregnancy are: ▪ 1 out of 10 children will have physical birth defects. ▪ 3 to 4 out of 10 children will have early development problems that can lead to significant learning disabilities.	☐ Yes
That I have had a pregnancy test (if advised by my doctor);	☐ Yes
Why I must use effective contraception, without stopping or interruption, at all times while taking valproate;	☐ Yes
The options for effective long-term contraception (or a consultation has been planned with a professional who can give me advice);	☐ Yes
The need to consult with my doctor as soon as I start thinking about becoming pregnant. This is to make sure I have time to switch to another treatment before I come off contraception;	☐ Yes
That I should request an urgent doctor's appointment if I think I am pregnant;	☐ Yes
That I have a copy of the Patient Guide and know where to find more information.	☐ Yes
In case of pregnancy, I confirm that: ▪ I have considered and discussed options for switching treatment. ▪ I am fully aware of the risks and I have the opportunity to have counselling about the risks.	☐ Yes ☐ Yes

Effective contraception is essential while taking valproate. Neither condoms nor oral contraceptives alone are sufficient. Long term contraceptives are strongly recommended such as a coil (copper intrauterine device {IUD}) or levonorgestrel intrauterine system for example Mirena® or contraceptive implant (for example Implanon®) or sterilisation.

Contraceptive currently used and date of insertion if applicable:

_____

Name of valproate user: _____

Name of responsible person if applicable: _____

Signature: _____ **Date:** _____

This form expires in 12 months from this date. A new form should be completed at each annual review.

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Valproate Annual Risk Acknowledgement Form for prescriber

If a woman uses valproate while she is pregnant, her child may be harmed. This form confirms that you have explained the risks of using valproate.

Name of valproate user: _____

Name of responsible person if applicable: _____

Name and signature of specialist or doctor: _____

Name of facility: _____

Date: _____

Part B: To be completed and signed by the specialist or doctor	
I confirm that the above-named patient needs valproate because: ▪ her condition does not respond adequately to other treatments, or ▪ she does not tolerate other treatments.	☐ ☐
I confirm that I have discussed the following information with the person named above:	
Valproate must not be used during pregnancy (except in rare situations in epilepsy for patients who are resistant or intolerant to other treatments);	☐ Discussed
The overall risks in children exposed to valproate during pregnancy are: ▪ An approximately 10% chance of birth defects. ▪ A 30 to 40% chance of a wide range of early developmental problems that can lead to learning disabilities.	☐ Discussed
The conditions of pregnancy prevention programme must be fulfilled;	☐ Discussed
The need for regular (at least annually) review of the need to continue valproate treatment by a doctor;	☐ Discussed
The need for effective contraception, without interruption, throughout treatment with valproate;	☐ Discussed
The need to arrange an appointment with her doctor as soon as she is planning pregnancy to ensure timely discussion and switching to an alternative treatment before conception and before stopping contraception;	☐ Discussed
The need to contact a doctor immediately for an urgent review of her treatment in case of suspected or inadvertent pregnancy;	☐ Discussed
The patient or caregiver/legal representative has a copy of the patient guide;	☐ Discussed
The need for a negative serum pregnancy test result at start and if needed thereafter.	☐ Discussed
In case of pregnancy, I confirm that: ▪ We have discussed options for switching treatment. ▪ She is fully aware of the risks of pregnancy and has the opportunity for counselling about risks.	☐ ☐
Comments:	

A copy of the completed and signed form must be given to the patient or responsible person (if applicable) and the original should be kept in the patient file at the clinic/hospital.

This form expires 12 months from the date of signature. A new form should be complete at each annual review.

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

Date: 30 November 2018

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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