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Sodium valproate/valproic acid – Annual Risk Acknowledgement Form

Annual risk acknowledgement form (ARAF)

Valproate is highly teratogenic

- use in pregnancy leads to neurodevelopmental disorders and congenital malformations.
- must not be used in women of childbearing potential unless conditions of pregnancy prevention programme (PPP) are met.

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Annual risk acknowledgement form

- Part of a PPP (risk management plan):
- Helps to monitor the risks,
- documents patient's awareness of risks,
- reinforces the PPP,
- promotes informed decision making,
- ensures compliance monitoring to ensure prescribers follows treatment guidelines.

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Annual risk acknowledgement form

- Prepared in collaboration with NDOH and the pharmaceutical industry.

- Published on the SAHPRA website https://www.sahpra.org.za/document/valproate-annual-risk-acknowledgement-form/

- Valproate holders of certificate of registration provide access to the form (via physical distribution/ digital platforms).

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Revision of the ARAF

- SAHPRA revised the valproate ARAF based on the NEMLC's review of the STGs for the management of seizures and epilepsy which highlighted the following:
    - the form currently refers to the involvement of a specialist yet there is a lack of equitable access to medical specialists in the public sector
    - The current form alternates between 'doctor/specialist' and 'GP'.
    - the recommendation to revise the wording on the form from specialist to medical practitioner (doctor)" based on the attached forms

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Old form

Doc Number: GLF-CEM-PV-S01 *[Old Doc no. 6.28]*	VALPROATE ANNUAL RISK ACKNOWLEDGEMENT FORM	SAHPRA South African Health Products Regulatory Authority
Revision: 1.0		Effective date: 22 July 2022

VALPROATE HAS RISKS IN PREGNANCY

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 my specialist, and I understand:	
Why I need valproate rather than another medicine	☐ Yes
That I should visit a specialist 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 birthdefects • 3 to 4 out of 10 children will have early developmental problems that can lead to significant learning disabilities	☐ Yes
That I have had a pregnancy test (if advised by my doctor/specialist)	☐ 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 my specialist or GP 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 GP 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 have the opportunity to have counselling about the risks	☐ 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) and contraceptive implant (progestogen-only implant) or sterilisation.

Contraceptive currently used: .....

Name of valproate user: .....

Name of responsible person (if applicable): .....

Signature: ..... **Date**: .....

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

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Doc Number: GLF-CEM-PV-S01 *[Old Doc no. 6.28]*	**VALPROATE ANNUAL RISK ACKNOWLEDGEMENT FORM**	SAHPRA South African Health Products Regulatory Authority
Revision: 1.0		Effective date: 22 July 2022

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, role, and signature of specialist: .....

Name of valproate user's GP: ..... **Date:** .....

Part B. To be completed and signed by the specialist	
I confirm that the above-named patient needs valproate because: • her condition does not respond adequately to othertreatments, 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 the pregnancy prevention programme must be fulfilled	☐ Discussed
The need for regular (at least annual) review of the need to continue valproate treatment by a specialist	☐ Discussed
The need for effective contraception, without interruption, throughout treatment with valproate	☐ Discussed
The need to arrange an appointment with her specialist 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 her GP 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, has opportunity for counsellingabout risks ☐	

The specialist must provide this form to girls and women of childbearing potential treated with valproate (e.g. Epilim, Epilizine, Navalpro, Eprolep, Adco Sodium Valproate, Valeptic, Sandoz Sodium Valproate, Cerepiv and Convulex) - or to their "responsible person": a parent/legal guardian or person capable of giving consent on behalf of patients who are minors or without the capacity to make an informed decision or person acknowledging that the treatment is in the best interests of the patient.
A copy of the completed and signed form shall be kept/recorded by the specialist. The prescriber is advised to save an electronic version in the patient dossier. *Copies of the completed and signed form should be given to the patient and also sent to their GP.*

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

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New form (latest version)

Doc Number: GLF-CEM-PV-S01	VALPROATE ANNUAL RISK ACKNOWLEDGEMENT FORM	SAHPRA South African Health Products Regulatory Authority
Revision: 2.0		Effective date: 25 April 2025

VALPROATE HAS RISKS IN PREGNANCY

If you use valproate while you are pregnant, there is a significant risk of serious harm to your child which may be identified at birth or early development. This form confirms that you or your caregiver/parent/responsible person understand the risks of using valproate (contained in medicines such as Epilim, Epilizine, Navalpro, Eprolep, Adco Sodium Valproate, Valeptic, Sandoz Sodium Valproate, Cerepiv and Convulex).

Part A: To be completed and signed by the valproate user and/or caregiver/parent or responsible person	
I have discussed the following with my Medical Practitioner (Doctor), and I understand:	
Why I need valproate rather than another medicine	☐ Yes
That I should visit a Medical Practitioner (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 developmental problems that can leadto significant learning disabilities	☐ Yes
That I have had a pregnancy test (if advised by my Medical Practitioner (Doctor) or other health professional)	☐ 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 health professional who can give me advice)	☐ Yes
The need to consult my health professional 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 health professional 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 have the opportunity to have counselling about the risks	☐ 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) and contraceptive implant (progestogen-only implant) or sterilisation.

Contraceptive currently used: .....

Name of valproate user: .....

Name of responsible person (if applicable): .....

Signature: ..... **Date:** .....

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

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Doc Number: GLF-CEM-PV-S01	VALPROATE ANNUAL RISK ACKNOWLEDGEMENT FORM	SAHPRA South African Health Products Regulatory Authority
Revision: 2.0		Effective date: 25 April 2025

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, role, and signature of Medical Practitioner: .....
Name of valproate user's health professional: ..... **Date:** .....

Part B: To be completed and signed by the Medical Practitioner	
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: • 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 the pregnancy prevention programme must be fulfilled	☐ Discussed
The need for regular (at least annual) review of the need to continue valproate treatment by a Medical Practitioner	☐ Discussed
The need for effective contraception, without interruption, throughout treatment with valproate	☐ Discussed
The need to arrange an appointment with her Medical Practitioner or other healthcare professional 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 her Medical Practitioner or other healthcare professional 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, has an opportunity for counselling about risks ☐	

The Medical Practitioner must provide this form to girls and women of childbearing potential treated with valproate (e.g. Epilim, Epilizine, Navalpro, Eprolep, Adco Sodium Valproate, Valeptic, Sandoz Sodium Valproate, Cerepiv and Convulex) - or to their "responsible person": a parent/legal guardian or person capable of giving consent on behalf of patients who are minors or without the capacity to make an informed decision or a person acknowledging that the treatment is in the best interests of the patient.

A copy of the completed and signed form shall be kept/recorded by the Medical Practitioner. The prescriber is advised to save an electronic version in the patient dossier. *Copies of the completed and signed form should be given to the patient and also sent to their other health professional, as needed.*

***NOTE:** This form expires 12 months from the date of signature. A new form should be completed at each annual review.*

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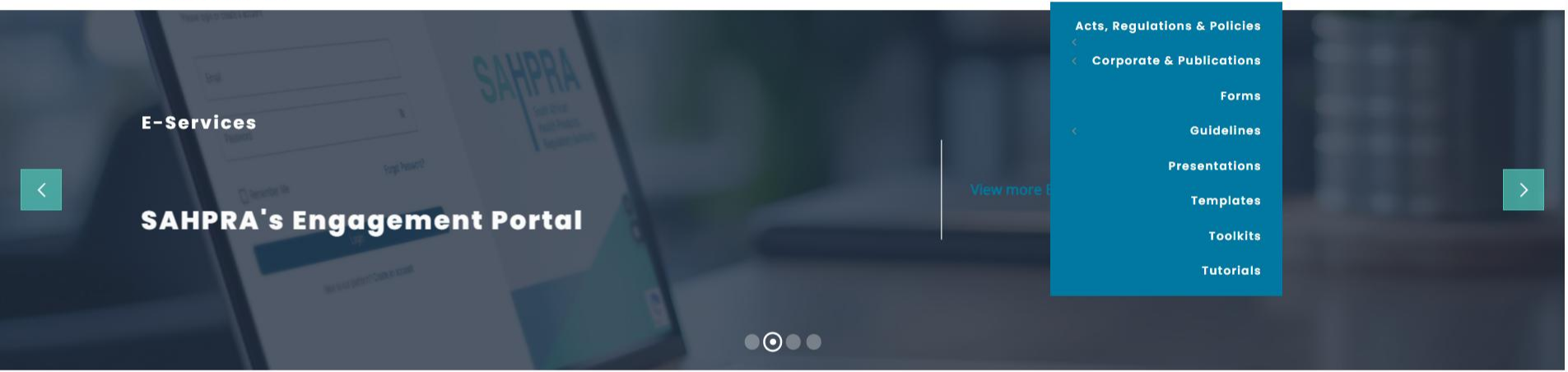

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Part A: To be completed and signed by the valproate user and/or caregiver/parent or responsible person	
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That I have had a pregnancy test (if advised by my Medical Practitioner (Doctor) or other health professional)	☐ Yes
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The options for effective long-term contraception (or a consultation has been planned with a health professional who can give me advice)	☐ Yes
The need to consult my health professional 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
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Contraceptive currently used: .....

Name of valproate user: .....

Name of responsible person (if applicable): .....

Thank you

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