Annual Risk Acknowledgement Form
Valproate (Epilim▼) and Risks in Pregnancy

prevent
valproate pregnancy prevention programme

Name of Patient: **Date of Birth:**

MRN:

Name & Role of Specialist:

Name of Patient's GP:

Children exposed to valproate in utero have a very high risk for congenital malformations and neurodevelopmental disorders. Valproate is therefore contraindicated in women of childbearing potential (i.e. a pre-menopausal female who is capable of becoming pregnant) unless the conditions of 'prevent', the valproate (Epilim) pregnancy prevention programme are fulfilled.

- Specialists should complete and sign the Annual Risk Acknowledgement Form (ARAF) with a female patient of childbearing potential treated with valproate.
- The ARAF discussion ensures female patients understand why they are prescribed valproate and the need to prevent pregnancy due to the risks for children exposed in utero.
- Discuss and complete the ARAF at treatment initiation (or when menarche is reached), at the annual visit, or when a pregnancy is planned.
- The ARAF can be completed with a parent/legal guardian when appropriate (e.g. minors, patients without capacity to make an informed decision).
- In cases of pregnancy, the ARAF (part C) can be used as a basis for discussion.
- File the signed ARAF in the patient's medical record and give a copy to the patient and her GP.

Refer to the valproate (Epilim) **HCP guide** for full details on the requirements of **'prevent',** including use of the ARAF, and provide a copy of the valproate (Epilim) Patient Guide† to patients.

A follow-up appointment should be arranged at least every year to review the need for continued treatment with valproate and adherence to **'prevent'** measures.

A new form must be completed at each annual review.

This form expires on _____ **(12 months after completion).**

† Patient Guide and patient card can be found online at www.hpra.ie by entering "Epilim" or valproate in the 'Find a medicine' search box and then clicking on "EdM" next to any of the medicines that appear.

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Name of Patient:		**MRN:**	

Part A - Does 'prevent' apply to this patient?

Women of childbearing potential (i.e. pre-menopausal females who are capable of becoming pregnant) taking valproate, regardless of the indication, should fulfil all the requirements of the **'prevent'** pregnancy prevention program. The only exception is when you (the specialist) consider that there are compelling reasons to indicate that there is no risk of pregnancy. When initiating or reviewing treatment, carefully assess the potential for pregnancy and decide if **'prevent'** applies to this patient (see below).

Specialist Assessment	**Tick box**
The patient is of childbearing potential and **'prevent'** applies (sign Part A and proceed to B and C)	☐
The patient is of childbearing potential, however, there are compelling reasons to indicate there is no risk of pregnancy and the requirements of **'prevent'** do not apply (record reasons here and sign Part A):	☐

Note: If the compelling reason(s) may be subject to change (not permanent), the patient should be advised to contact her specialist immediately if her circumstances change, and a regular review of the reason should be undertaken as part of treatment reviews and at least annually. The patient should be provided with a copy of the patient guide and the risks of pregnancy explained so that she is aware of the risks if circumstances change. Parts B and C of the form can be completed to aid discussion and understanding.

For girls that have not yet reached menarche, parents/legal guardians should be advised of the need to contact the specialist as soon as menarche occurs to arrange for a review of treatment. The patient and/or her parents/legal guardian should be provided with a copy of the patient guide and the risks of pregnancy explained so that they are aware of the risks for the future. Parts B and C of the form can be completed to aid discussion and understanding, where appropriate.

I confirm that, where applicable, I have given the patient (and/or her parent/legal guardian) a copy of the valproate (Epilim) patient guide and informed her that an electronic version of the patient guide, patient card and package leaflet can be accessed at www.hpra.ie†	☐

Name of Specialist:

Signature: _____

Date:

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Name of Patient:		**MRN:**	

Part B: Specialist acknowledgement that risks related to the use of valproate during pregnancy and the requirements of 'prevent' were discussed with the patient

I confirm I have discussed the following with the patient:	**Initials**
The patient needs valproate because: ☐ her condition does not respond adequately to other treatments ☐ she does not tolerate other treatments ☐ she is currently undergoing a treatment change from valproate	
Valproate must not be used during pregnancy (except in rare situations in epilepsy for patients who are resistant or intolerant to other treatments)	
The overall risks in children exposed to valproate during pregnancy are: • an approximately 10% chance of birth defects • up to 30% to 40% chance of a wide range of early developmental problems that can lead to significant learning disabilities	
The conditions of the pregnancy prevention programme must be fulfilled when of childbearing potential	
The need for regular (at least annual) review of the need to continue valproate treatment by a specialist	
The need for a negative (serum) pregnancy test result at treatment initiation and as needed thereafter (when of childbearing potential)	
The need for effective contraception, without interruption, throughout treatment with valproate (when of childbearing potential)	
The need to arrange an appointment with her specialist as soon as she is planning pregnancy to ensure timely discussion, and a timely switch to an alternative treatment before stopping contraception and conception occurring	
The need to contact her doctor immediately for an urgent referral and review of treatment by her specialist in case of suspected pregnancy	
I confirm I have given the patient (and/or her parent/legal guardian) a copy of the valproate (Epilim) patient guide and informed her that an electronic version of the patient guide, patient card and package leaflet can be accessed at www.hpra.ie†	
In case of pregnancy, I confirm that:	
• We have discussed options for switching treatment	
• She is receiving the lowest possible effective dose of valproate to minimise the possible harmful effect on the unborn	
• She is fully aware of the risks of pregnancy	
• She is informed about the possibility of pregnancy support or counselling and appropriate monitoring of her baby during pregnancy	
• I confirm I have given the patient (and/or her parent/legal guardian) a copy of the valproate (Epilim) patient guide and informed her that an electronic version of the patient guide, patient card and package leaflet can be accessed at www.hpra.ie†	
Clinical notes (as applicable):	

Name of Specialist:

Signature: _____ **Date:**

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Name of Patient:		**MRN:**	

Part C: Patient acknowledgement that the risks of valproate use during pregnancy and the requirements of 'prevent' are understood

To be completed by the patient and signed by her (or parent /legal guardian if applicable*) and her specialist	**Initials**
I have discussed the following with my specialist and I understand:	
• Why I need valproate rather than another medicine	
• That I should visit a specialist regularly (at least once a year) to review whether valproate remains the best option for me.	
• If I use valproate while I am pregnant, my baby has significant risk of serious harm	
The overall risks in children whose mothers took valproate during pregnancy are: • approximately 10 babies in every 100 will have birth defects and • up to 30 to 40 children in every 100 may have a wide range of early developmental problems that can lead to significant learning difficulties	
• Why I need a negative pregnancy test at the start of treatment and as needed thereafter	
• The reasons why I must use effective contraception, without stopping or interruption, at all times while taking valproate	
• The options for effective contraception (or a consultation has been planned with a professional who can give me advice)	
• The need to consult my specialist or GP (who will refer me to the specialist) as soon as I start thinking about becoming pregnant. This is to make sure I have time to switch to another treatment before I stop contraception.	
• That I should request an urgent appointment with my specialist if I think I am pregnant	
• I have received a copy of the valproate (Epilim) patient guide and understand that I can access www.hpra.ie for an electronic version of the patient guide, patient card or package leaflet†.	
In case of pregnancy, I have discussed the following with my specialist and understand:	
• The options for switching treatment	
• The risks of valproate use in pregnancy	
• The possibilities of pregnancy support or counselling	
• The need for appropriate monitoring of my baby	

Name of Patient:

Signature: _____ **Date:**

If applicable, name of person signing on behalf of patient: *

Relationship to patient (parent/legal guardian):

Signature: _____ **Date:**

Name of Specialist:

Signature: _____ **Date:**

* for patients who are minors or without the capacity to make an informed decision.
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