Does 'prevent' apply to my patient?

prevent
valproate pregnancy prevention programme

Patient Name:		**MRN:**	

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 the prevent valproate (Epilim▼) pregnancy prevention programme are fulfilled.

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 your patient.

Specialist Assessment	**Tick box**
The patient is of childbearing potential and **prevent** applies (the annual risk acknowledgement form [ARAF] must be completed together with the patient. Refer to Healthcare Professional guide[†] for further details)	☐
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):	☐

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. The ARAF 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[†]. The ARAF can be completed to aid discussion and understanding, where appropriate.

Name of Specialist:	
Signature:	
Date:	

[‡] See the 'Overall risks in children' box of the ARAF for further details.

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

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

prevent
valproate pregnancy
prevention programme

Patient Name:		**MRN:**	

As part of the prevent valproate pregnancy prevention programme, this form must be completed together with the patient at treatment initiation, annual visits, and in case of pregnancy or planning for pregnancy.

To be completed by the patient (or parent/legal guardian if applicable)*	**Tick box**
I have discussed the following with my specialist and I understand:	
• Valproate must not be used during pregnancy. The only exception is rare situations in epilepsy for patients who are resistant or intolerant to other treatments and only at the lowest possible effective dose to minimise the possible harmful effect on the baby	☐
• Why I need valproate rather than another medicine: ☐ My condition does not respond adequately to other treatments ☐ I do not tolerate other treatments ☐ I am currently undergoing a treatment change from valproate	
• 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 11 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 • children are more likely to have autism or autistic spectrum problems and are at increased risk of developing Attention Deficit Hyperactivity Disorder (ADHD)	☐
• Why I need a negative serum 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†	☐
In case of pregnancy, I have discussed the following with my specialist, and I understand:	
• Valproate must not be used during pregnancy. The only exception is rare situations in epilepsy for patients who are resistant or intolerant to other treatments and only at the lowest possible effective dose to minimise the possible harmful effect on the baby	☐
• The options for switching my treatment	☐
• The risks of valproate use in pregnancy	☐
• The possibilities of pregnancy support or counselling and appropriate monitoring of my baby	☐
• I have received a copy of the valproate (Epilim) patient guide†	☐

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

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

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

prevent
valproate pregnancy
prevention programme

Patient Name:		**MRN:**	

To be completed by the specialist	**Tick box**
• This patient needs treatment with valproate because (tick as applicable):	
– The patient's condition does not respond adequately to other treatments	☐
– The patient does not tolerate other treatments	☐
– The patient is currently undergoing a treatment change from valproate	☐
• I have discussed with my patient the risks of taking valproate during pregnancy and the measures that need to be taken, as set out above, and have confirmed my patient's understanding	☐
• In case of pregnancy, I confirm I have discussed with my patient all of the above and the patient is on the lowest possible effective dose to minimise the possible harmful effect on the baby	☐

To be signed by the patient and specialist	
Name of Patient:	
Signature:	
Date:	

Name of person signing on behalf of the patient, if applicable*	
Signature:	
Date:	

Name of Specialist:	
Signature:	
Date:	

File the completed form in the patient's medical record and provide a copy to the patient. It is recommended that the patient's GP is informed, per local institutional practice.

A new form must be completed at each annual review.

This form is due to be completed again at the next annual visit ☐ **(12 months after completion), or earlier in case of pregnancy/planning for pregnancy**

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