Annual Risk Acknowledgement Form for Female Patients

VALPROATE▼ HAS RISKS IN PREGNANCY

Children exposed to valproate during pregnancy have a high risk for congenital malformations, neurodevelopmental disorders and lower weight at birth for gestational age.

Valproate should not be used in female patients aged under 55 years unless two specialists (specialist prescriber and countersigning specialist) independently consider and document, in this form, that there is no other effective or tolerated treatment. This form outlines the conditions of prevent - the valproate Pregnancy Prevention Programme and when these must be fulfilled.

Female patients who have a permanent reason that they do not have the potential to get pregnant (e.g., post-menopausal patients or those after hysterectomy) do not need to complete this form beyond step 1. This form can be used to support documentation in the medical notes that prevent does not apply to this patient.

- This form is used to support and record the prescribing decision and, where applicable, discussion with the patient or their responsible person of the risks associated with the use of valproate during pregnancy and the measures needed to minimise the risks in female patients.
- The specialist prescriber must provide this form to female patients treated with valproate (Epilim, Depakote, Alprolep, Belvo, Convulex, Dyzantil, Episenta, Epival, Syonell & Sodium Valproate (Crescent, Desitin, Strandhaven/Somex, Wockhardt)) – or to their "responsible person" i.e., 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.
- The decision of the countersigning specialist must be documented in step 2. A countersigning specialist is only required for patients newly starting valproate and for existing female patients at one annual review. Subsequent annual reviews do not require the countersigning specialist unless the patient's circumstances have changed. The date of the second specialist review should be included in this and all subsequent ARAFs.
- This document can be completed electronically, wet signatures are not required.

Once completed, a copy of this form should be given to the patient or their responsible person and stored in their medical notes, it should also be shared with all healthcare professionals listed in the table below.

Name of patient:

Patient's date of birth:

Patient's NHS number:

Patient's hospital number:

Name and contact details of specialist prescriber:

Role and unique identifier:

Signature of specialist prescriber:

Date of signature:

Name of countersigning specialist:

Role and unique identifier:

Signature of countersigning specialist (if needed specialist prescriber can sign here to confirm that discussion with countersigning specialist has occurred):

Date of signature: *This date should be included in step 2 within this ARAF and all subsequent ARAFs.*

Name and address of patient's General Practitioner (GP):

Date form completed:

WARNING: Prescribing valproate to a woman of childbearing potential without the conditions of **prevent - the Pregnancy Prevention Programme** being fulfilled is contraindicated and represents an unlicensed use of the drug. Use of valproate during pregnancy for bipolar disorder, and during pregnancy for epilepsy (unless there is no other effective or tolerated treatment), are both unlicensed. This is the case even when treatment is based on an informed choice made by the patient.

Risk minimisation material fulfils the conditions of the marketing authorisation and has been approved by MHRA.

More information can also be found online at www.medicines.org.uk by entering "valproate" in the search box and then clicking on "Risk Materials" next to any of the medicines listed.

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Step 1 – Specialist prescriber: Establish whether the patient is at risk of the reproductive harms of valproate

The following issues should be considered when evaluating the risks associated with the use of valproate during pregnancy:

- Women of childbearing potential (from menarche to menopause) who are taking any medicine containing valproate, regardless of the indication, should fulfil all the conditions of **prevent** unless there are compelling reasons that there is no risk of pregnancy which should be documented below.
- If the potential for not becoming pregnant is permanent, the reason should be documented below and the conditions of **prevent** **DO NOT** need to be fulfilled.
- Female children who have not yet reached menarche (not started her periods) **DO NOT** need to fulfil the conditions of **prevent**, but they and their responsible person need to be aware of the risks for the future. You should provide a copy of the Patient Guide and remind the responsible person to contact their GP once the female child using valproate experiences menarche. Their GP will refer the patient back to the specialist prescriber.
- If the compelling reason(s) suggesting no risk of pregnancy may be subject to change, the risks should be discussed and acknowledged at this, and subsequent annual reviews or sooner if their circumstances change.

If you consider there is a reason that indicates **prevent** does not apply, *tick* which reason applies and record here. If the reason is permanent, steps 2, 3 and 4 do not need to be completed.

To be completed by the specialist prescriber if they consider prevent - the valproate Pregnancy Prevention Programme (PPP) - is not needed
☐ The patient has not yet reached menarche at the time of this appointment. I have asked the patient and their family to inform their GP to refer the patient back to the specialist prescriber if this changes before their next annual review.
☐ The absence of pregnancy risk is considered to be permanent for the following reason (*insert reason*):
☐ There are other reasons that conditions of **prevent** are not applicable (*insert reason*):

To be completed by the patient if they consider prevent - the valproate pregnancy prevention programme (PPP) does not apply to them	
☐ I confirm that I agree the risks of valproate and therefore **prevent** do not apply to me.	
Name of patient:	
Name of responsible person (if applicable):	
Signature of patient (or responsible person):	**Date:**

Patients who have completed the declaration in the box above do not need to complete step 4 on this form.

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Step 2: Specialist prescriber and countersigning specialist: Document the prescribing decision.

Actions to be completed by the specialist prescriber to confirm the prescribing decision	Initial to confirm
• The patient's condition does not respond to other treatments or other treatments are not tolerated.	

To be completed by the countersigning specialist (can be completed by specialist prescriber following discussion with countersigning specialist if needed). This section is to be completed once and then carried forwards for subsequent annual reviews, unless the patient's circumstances have changed.	Date of second specialist review (this date should be included to all future ARAFs)
• I confirm that this patient should be treated with valproate.	
• The patient's condition does not respond to other treatments or other treatments are not tolerated.	

Step 3: Specialist prescriber: Explain the risks to the patient or responsible person.

The risks must be discussed with the patient or their responsible person (if applicable), and the patient (or responsible person) must sign the subsequent section of this form to confirm they have discussed and acknowledge the risks of taking valproate during pregnancy.

Information to be discussed with the patient or their responsible person	Initial to confirm you have discussed
I have discussed the following risks with the patient and consider the balance of benefits and risks to be positive.	
That their medication should be reviewed regularly (at least once a year) and their medication may need to be changed if their circumstances change, increasing the risks.	
That valproate can cause serious harm to an unborn baby if taken by a mother during pregnancy, which may lead to permanent disability. The overall risks in children exposed to valproate during pregnancy are: • an approximately 11% chance of physical birth defects • up to a 30% to 40% chance of neurodevelopmental disorders • a lower weight than expected for their age at birth	
Explain the conditions of **prevent - the Pregnancy Prevention Programme** and why these must be fulfilled.	
The need for a negative (ideally serum) pregnancy test result before starting treatment with valproate and, if needed, further pregnancy tests at appointments thereafter.	
The need to use effective birth control (contraception), without interruption, throughout treatment with valproate.	
The need to consult their general practitioner (GP) for referral to the specialist as soon as they are planning pregnancy to ensure timely discussion and switching to another treatment before the child is conceived and before birth control (contraception) is discontinued.	
The need for the patient to contact their GP immediately, to be urgently referred to their specialist prescriber for an urgent review of their treatment in case of suspected or unplanned pregnancy.	
Explain the risks of stopping valproate without medical advice. Patients on valproate should not stop taking their medicine or change their dose unless they are told to do so by a specialist. This is because their condition may become worse, including an increase in seizures in patients treated for epilepsy and an increased risk of relapse in patients treated for bipolar disorder.	
I have offered the patient a copy of the Patient Guide and they know where to get further information.	

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Step 4: To be completed by the patient or responsible person

Completing this section of the form confirms that you, the patient (or your responsible person), have discussed and acknowledge the risks of using valproate during pregnancy and the measures needed to reduce the risk with your specialist prescriber.

It is recommended that you keep a copy of this form which will also be added to your medical notes.

I have discussed the benefits and risks of valproate compared to other treatments with my specialist prescriber and I acknowledge that:	**Initial to confirm you acknowledge each item**
My medication should be reviewed regularly (at least once a year) and may need to be changed depending on my circumstances.	
Valproate can cause serious harm to an unborn baby if taken by a mother during pregnancy and may lead to permanent disability. The risks in children whose mothers took valproate during pregnancy are: • An approximately 11% chance of physical birth defects • Up to 30% to 40% of children may have problems with early childhood development. Children affected can be slow to walk and talk, intellectually less able than other children, and have difficulty with language and memory, or problems with development (behaviour and learning disorders) which can be seriously debilitating and/or permanent • a lower weight than expected for their age at birth	
I am aware of the need to have a negative pregnancy test before starting treatment with valproate and if needed, further pregnancy tests at subsequent appointments.	
I am aware of the need to use an effective method of birth control (contraception), without stopping or interruption, while taking valproate.	
The options for effective long-term methods of birth control (contraception) have been discussed (or a consultation has been planned with a professional who can give me advice).	
I need to consult my GP to be referred to my specialist prescriber 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 birth control (contraception).	
I should request an urgent appointment with my GP, to be urgently referred to my specialist prescriber, if I think I am pregnant.	
I have been offered a copy of the valproate Patient Guide and know where to find more information online using the QR code on the leaflet in the pack.	
I should not stop valproate or change the dose unless told to do so by my specialist as my condition may become worse, including an increase in seizures in patients treated for epilepsy and an increased risk of relapse in patients treated for bipolar disorder.	
Name of patient:	
Name of responsible person (if applicable):	
Signature of patient (or responsible person):	**Date:**

▼ This Medicinal Product is subject to additional monitoring. This will allow quick identification of new safety information.

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme, via the Yellow Card website www.mhra.gov.uk/yellowcard, the free Yellow Card app available in Apple App Store or Google Play Store, and also some clinical IT systems for healthcare professionals. Alternatively, you can call 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible. By reporting adverse drug reactions, you can help provide more information on the safety of this medicine.

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