South West Yorkshire Partnership NHS Foundation Trust

VALPROATE Annual Risk Acknowledgement Form (Patient)

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

Part A. To be completed and signed by the valproate user and/or carer/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 birth defects • 3 to 4 out of 10 children will have early developmental problems that can lead to significant learning disabilities	 ☐ Yes ☐ 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 ☐ 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: …….

NHS Number: …….

Name of responsible person (if applicable): ……

Signature: …… Date: ……

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

With **all of us** in mind.

VALPROATE Annual Risk Acknowledgement Form (Specialist)

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: ……

NHS Number: ……

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 other treatments, or • she does not tolerate other treatments I confirm that I have discussed the following information with the person named above:	☐ Discussed ☐ Discussed
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 including sharing of this form	☐ 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 counselling about risks	☐ Discussed ☐ Discussed

The specialist must provide this form to girls and women of childbearing potential treated with valproate (Epilim, Depakote, Convulex, Episenta, Epival, Kentlim, Orlept, Syonell, Valpal)- 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 on SystmOne and on a valproate register. Copies of the completed and signed form should be given to the patient and also sent to their GP.

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