Annual Risk Acknowledgement Form

VALPROATE HAS RISKS IN PREGNANCY

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 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: • 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 counselling about risks ☐

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. 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.*

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