

Annual Risk Acknowledgement Form

VALPROATE ▼HAS RISKS IN PREGNANCY

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 understand 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	<input type="checkbox"/> Yes
That I should visit a specialist regularly (at least once a year) to review whether valproate remains the best option for me	<input type="checkbox"/> Yes
The risks in children whose mothers took valproate during pregnancy are: <ul style="list-style-type: none">• 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	<input type="checkbox"/> Yes
That I have had a pregnancy test (if advised by my doctor/specialist)	<input type="checkbox"/> Yes
Why I must use effective contraception, without stopping or interruption, at all times while taking valproate	<input type="checkbox"/> Yes
The options for effective long-term contraception (or a consultation has been planned with a professional who can give me advice)	<input type="checkbox"/> 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	<input type="checkbox"/> Yes
That I should request an urgent GP appointment if I think I am pregnant	<input type="checkbox"/> Yes
That I have a copy of the Patient Guide and know where to find more information	<input type="checkbox"/> Yes
In case of pregnancy, I confirm that: <ul style="list-style-type: none">• 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	<input type="checkbox"/> 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:

Name of responsible person (if applicable):

Signature: **Date:**

This checklist is intended to be used at time of treatment initiation and annual review by physicians experienced in the management of epilepsy to facilitate a discussion with girls and WCBP patients and/or their carers about the suitability of a treatment with valproate and its risks.

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: Discussed

- 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.

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) - 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 checklist is intended to be used at time of treatment initiation and annual review by physicians experienced in the management of epilepsy to facilitate a discussion with girls and WCBP patients and/or their carers about the suitability of a treatment with valproate and its risks.

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