

Risk Acknowledgement Form

FOR MALE PATIENTS STARTING VALPROATE

This form is used for new male patients starting a medicine containing valproate.

Valproate should not be started in male patients aged under 55 years unless two specialists consider and document that there is no other effective or tolerated treatment or the risk of infertility or potential risk of testicular toxicity do not apply.

This form applies to male patients aged under 55 years because this is the age group most likely to be affected by the risk of infertility and the potential risk of testicular toxicity. However, if these risks do not apply (e.g., the patient is permanently infertile), the countersigning specialist is not required, and the specialist prescriber should use this form to document the reason and record in the patients notes.

- This form is to support and record the discussion of risks with male patients aged under 55 years starting treatment with valproate or their responsible person or parents/care givers (if applicable).
- The specialist prescriber must provide this form to male patients aged under 55 years being started on valproate (Epilim, Depakote, Convulex, Episenta, Epival, Sodium Valproate, Syonell, Belvo & Dyzantil) – or to their “responsible person”.
- In this instance, a responsible person is 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 countersigning specialist must document their decision.

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:

Name and address of patient’s GP:

Date form completed:

Step 1: 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 all that apply
• The patient's condition does not respond adequately to other treatments or other treatments are not tolerated.	
• I have discussed the risks with the patient, and I consider the balance of benefits and risks to be favourable.	
• I have offered the patient a copy of the Patient Guide and they know where to get further information.	
• The risk of infertility or potential risk of testicular toxicity do not apply for the following reason(s):	

To be completed by the countersigning specialist prescriber (can be completed by specialist prescriber following discussion with countersigning specialist, if needed)	Initial to confirm all that apply
• Their condition does not respond to other treatments or other treatments are not tolerated.	
• They have been informed of the risks and I consider the balance of benefits and risks to be favourable.	

Step 2: Specialist prescriber: Explain the risks to the patient or responsible person

Information to be discussed with the patient or responsible person	Initial to confirm you have discussed
Fertility while on valproate <ul style="list-style-type: none"> • Valproate may cause infertility in some male patients. This can make it difficult to have a baby. • Male infertility may be reversible after valproate is stopped or after a dose reduction in some patients. 	
Effects on male reproductive system <ul style="list-style-type: none"> • Some studies in male animals have shown valproate to have an adverse effect on parts of the male reproductive system. These include toxic effects on the testes (testicles). • The weight of the developing testes (testicles) was lower in young animals given valproate and it is unclear what this means for humans. 	
Risks of stopping valproate without medical advice <ul style="list-style-type: none"> • 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. 	

Step 3: 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 risk of male infertility, and the toxic effect of valproate on the testes of animals using valproate. 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
• Valproate may cause infertility in some male patients and that this infertility may be reversible after valproate is stopped or after the dose is reduced for some patients.	
• There are animal studies showing that valproate may have an effect on testes (testicles) and it is unclear what this means for humans.	
<ul style="list-style-type: none"> • 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. • If my condition becomes worse, I should contact my specialist straight away. 	
• I have been offered the Patient Guide and know where I can access this information online using the QR code on the leaflet in the pack.	
Name of patient:	
Name of responsible person (if applicable):	
Signature of patient (or responsible person):	Date: