Valproate dispensing guidance and checklist

In-utero exposure to valproate is associated with developmental disorders and congenital malformations, including spina bifida, malformations of the face, kidney and heart, late development in speech, lower intelligence and memory problems. Children exposed to valproate during pregnancy have:

- Up to a **40 per cent** increased risk of a developmental disability
- A **10 per cent** risk of birth defects

! Common valproate medicine brands include; **Epilim®**, **Episenta®** and **Depakote®** (as valproate semisodium/valproic acid)

Top tips for dispensing valproate

Action	Guidance
✓ Develop a process to highlight valproate prescriptions for females; incorporate into pharmacy standard operating procedures (SOP)	➢ Consider using alert stickers on prescription bags, shelf edge labels or automated Patient Medication Record (PMR) alerts
✓ Maintain stock of valproate resources (valproate patient guide and patient card)	➢ Available from the Medicines and Healthcare products Regulatory Agency (MHRA) website and as additional risk materials in the Summary of Product Characteristics (SPC) ➢ Resources can be ordered by contacting the valproate manufacturer directly
✓ Ensure clinical resources are available to refer to	➢ Use resources such as the British National Formulary (BNF), SPCs and National Institute for Health and Care Excellence (NICE)
✓ Contact the the prescriber where there is evidence of inappropriate valproate prescribing or the female has not been informed of the associated risks in pregnancy	➢ Check whether the prescriber is undertaking regular reviews - treatment should be at least annually reviewed by a specialist ➢ Is the prescriber aware of the prescribing recommendations and prescriber resources available on the MHRA website?
✓ Report any prescribing errors or suspected adverse effects	➢ Report prescribing errors via the NPA Patient Safety Incident report form (England and Scotland), the National Reporting and Learning System (NRLS) (Wales) and the Health and Social Care (HSC) Board anonymous reporting form (Northern Ireland) ➢ Report adverse effects via the Yellow Card Scheme
✓ Be familiar with the national valproate patient safety alerts	➢ England: NHS Improvement ➢ Wales: Patient Safety Wales ➢ Scotland: Healthcare Improvement Scotland ➢ Northern Ireland: Safety Quality and Standards Circulars

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Action	Completed (✘ or ✓)
1. Have other therapies been used to treat the patient's condition? Valproate should **only** be used in females (children, adolescents, pregnant and those of childbearing potential) if other treatments are **ineffective or not tolerated**	
2. Has the patient been **informed** of the risks associated with valproate use during pregnancy?	
3. Does the patient **understand** the risks associated with valproate use during pregnancy?	
4. Has the patient received a valproate **patient card**? If not, provide one	
5. Has the patient **read** the information, **signed** and **dated** the valproate patient card?	
6. Is the female using effective **contraception**?	
7. Remind the patient **not to** stop treatment abruptly and to **seek advice** when planning a pregnancy or if the female become pregnant	

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