

Medicines Matters

Issue 50 – 12th March 2026



This bulletin is part 2 in a series aimed to raise awareness of drugs within the Pregnancy Prevention Programme (PPP/Prevent); see [issue 46 \(Feb 26\)](#) for part 1

LSC Patient Safety Incident – valproate case study

A patient within LSC has recently become pregnant whilst prescribed valproate. The patient had indicated a desire to start a family but failed to follow medical advice and decided to stop taking valproate, putting herself at risk of seizures and increasing the likelihood of harm to the child due to no safe washout period. Medication continued to be prescribed during this time as the patient had not informed the practice of her decision.

A timeline of events helped to understand the situation in further detail. Thorough record-keeping by the practice showed all efforts had been made to support the patient, including use of an interpreter (due to a potential language barrier), ensuring the Annual Risk Acknowledgement Form (ARAF) was completed, discussion regarding highly effective contraception, regular appointments and follow-up with the patient.

Lessons continue to be learnt from these unfortunate cases; **primary care clinicians are reminded of their responsibility when prescribing these drugs in ensuring all aspects of the PPP are in place, AND for the need to concisely document all discussions and interventions.**

Reminder of the risks associated with valproate:

Despite all the work undertaken in LSC to raise awareness of PPP (Prevent), opportunities are being missed to ensure girls/women prescribed these drugs are risk assessed for safe use. This has resulted in pregnancies and significant risk of harm to the unborn child.

Valproate (sodium valproate/valproic acid/semi-sodium valproate; various brands available including *Epilim*) is approved in the UK to treat epilepsy and for manic episodes in bipolar disorder; see individual [SPCs](#) for further detail. ALL initiation regardless of indication should be by specialists, see [Lancashire and South Cumbria Formulary](#).

The use of valproate during pregnancy is associated with significant harm including a higher risk of congenital malformation, low birth weight and a potential increased risk of intellectual disability, autistic spectrum disorder and attention deficit hyperactivity disorder in children of mothers taking valproate during pregnancy [Valproate – reproductive risks - GOV.UK](#).

If valproate is used in females of childbearing potential, the conditions of the PPP need to be maintained throughout the period of use, irrespective of indication. **The PPP is designed to ensure patients are fully aware of the risks of valproate and agree to take steps to avoid becoming pregnant while taking this medicine.**

Recommendations for practices

- Ensure patients are aware of the risks in pregnancy and have a copy of the patient guide
- Ensure patients are continuously using highly effective contraception
- Ensure patients are receiving an annual review
- Ensure patients have an in-date signed ARAF **each time a prescription for valproate is issued**. Adding the ***expiry date of the ARAF to the medication directions will ensure it is easily visible to prescribers, secondary care and community pharmacies***
- Ensure prompt action if a patient reports a pregnancy or is planning a pregnancy

Click [here](#) for further information/links to resources on the safe use of valproate.

Report any safety incidents relating to valproate use via [Ulysses](#) and the [Yellow Card Scheme](#).