

Medicines Matters

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This bulletin is part of a series aimed to raise awareness of drugs within the Pregnancy Prevention Programme (PPP/Prevent)

LSC Patient Safety Incident – topiramate case study

A patient within LSC has recently become pregnant while prescribed topiramate. An annual risk awareness form (ARAF) had been completed by the initiating medical team in secondary care, yet the patient did not fully understand the need to prevent pregnancy.

These interface issues are being investigated to ensure all aspects of the PPP are clearly communicated to patients in a manner that can be fully understood. However, it is important for primary care clinicians to understand their responsibilities in ensuring all aspects for the PPP are in place **each time a prescription is issued**, including that the patient is continually using highly effective contraception.

Reminder of the risks associated with topiramate:

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.

Topiramate (brand name *Topamax*) is approved in the UK to treat epilepsy, and for migraine prophylaxis. It may also be prescribed outside of the licence ('*off label*') but this is usually specialist initiated - [Lancashire and South Cumbria Formulary](#).

The use of topiramate 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 topiramate during pregnancy [June 2024 Drug Safety Update](#).

If topiramate 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 topiramate 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 (process depends on indication)
- Ensure patients have an in-date signed ARAF **each time a prescription for topiramate is issued. A note can be added to the directions so that this is easily visible to prescribers and community pharmacies**
- Ensure prompt action if a patient reports a pregnancy or is planning a pregnancy (advice varies by indication)

Click [here](#) for further information/links to resources on the safe use of topiramate. Report any safety incidents relating to topiramate use via [Ulysses](#) and the [Yellow Card Scheme](#).