Medication Safety Series: MSS 30 | Topiramate▼ Pregnancy Prevention Programme

Tees, Esk and Wear Valleys
NHS Foundation Trust

Topiramate Safety Measures

See MHRA Drug Safety Update for full details.

The use of topiramate is now contraindicated:

- in people of childbearing potential unless the conditions of the Pregnancy Prevention Programme are fulfilled (for all indications)
    - See above link for details noting requirements including both an initial and annual risk acknowledgement form
- in pregnancy for prophylaxis of migraine
    - Usually initiated and reviewed by GPs
- in pregnancy for epilepsy unless there is no other suitable treatment
    - Specialist prescriber likely to be a neurologist

Although not stated by the MHRA, topiramate is also contraindicated in pregnancy for all off-label indications.

Supporting documentation

- Patient Guide [EPILEPSY] & Patient Card [EPILEPSY & MIGRAINE]
- Risk acknowledgement form [EPILEPSY]
- Healthcare Professional Guide [EPILEPSY]
- Pregnancy testing and contraception
- MHRA Guidance

Off-label indications

- The main use of topiramate in TEWV (except where continuing licensed indications for in-patients initiated elsewhere) is for off-label indications.
- For people of child-bearing potential topiramate is **not** on the pre-approved off-label indication list (for any indication).
- There is no national literature available to support a discussion on the risks vs. benefits of topiramate for off-label indications. For people of child-bearing potential the benefits are unlikely to outweigh the risks.
- In the exceptional circumstances, where topiramate is considered the most appropriate option, an application must be made which will be reviewed by a panel.
- If approved the applicant will be required to develop patient literature and an appropriate risk assessment form based on the national ones for epilepsy (see supporting documentation).
- This process applies before new initiation and on the first annual review of existing patients (to enable continued prescribing).

Prescribing topiramate: Dispensing Quantities

- Topiramate medicines should be dispensed (by community pharmacies & TEWV dispensaries) in the manufacturer's original full pack (new packs with warning labels will start to come into the supply chain in 2025).
- Additional warning labels should be applied to boxes that do not contain the warning (including pack down supplies).

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