

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
- pregnancy for prophylaxis of migraine
 - Usually initiated and reviewed by GPs
- 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](#) [TEWV off-label indications]
- [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 need to complete the local TEWV [risk acknowledgement form](#), for off-label indications, with the patient.
- The [choice and medication patient literature](#) must be provided to the patient.
- 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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