

July 2024 (updated)

Guidance note for the safe prescribing of topiramate

Topiramate is used in some patients for the treatment for epilepsy, other seizure disorders, and migraine. Exposure to topiramate in pregnancy is associated with significant harm to the unborn child, such as an increased risk of congenital malformations, autism spectrum disorders, intellectual disability, and neurodevelopmental disorders. Due to the accumulation of evidence of these harms, MHRA has issued new safety measures to further support prescribers around the safe use of topiramate in all women of childbearing potential and in pregnancy. The use of topiramate is now contraindicated:

1. in women of childbearing potential unless the conditions of the Pregnancy Prevention Programme are fulfilled (for all indications)
2. in pregnancy for prophylaxis of migraine
3. in pregnancy for epilepsy unless there is no other suitable treatment

Actions for primary care prescribing clinicians

- Do NOT initiate topiramate unless this is formally requested by the relevant specialist in neurology, mental health or migraine clinics.
- Initiate an EMIS (or SystmOne) [search](#) to identify patients prescribed topiramate.
- Continue to prescribe topiramate for existing patients, unless you are asked to stop prescribing by the patient’s specialist. Provide patients with information and reassurance, when needed.
- Ensure all patients are aware of the reproductive risks and risk of foetal harms when unborn children are exposed to topiramate during pregnancy.
- Ensure the conditions of the Pregnancy Prevention Programme are fulfilled. Refer to the guide for healthcare professionals for [Migraine](#) and [Epilepsy](#) for further information.
- Ensure existing women and girls of childbearing potential use a [highly effective method of contraception](#) and for at least four weeks after the last dose of topiramate. See [guidance from Faculty of Sexual and Reproductive Healthcare](#) on potential drug interactions with hormonal contraceptives and what this means for topiramate.
- Patients who are not recorded as under the care of a local specialist should be referred to the appropriate specialist using existing referral pathways.
- To minimise additional pressure for appointments on secondary care, please do not initiate new referrals for your existing patients who are known to consultant led clinics in secondary care. They will be invited for their **next annual specialist reviews** as a scheduled appointment.
- Ensure a topiramate pregnancy Risk Awareness Form (RAF) has been completed for all women and girls of child-bearing potential.
- Prescribe appropriate quantities so that pharmacists can dispense a manufacturer’s original full pack which will include all the necessary safety information for the patient.
- Where it is not in a patient’s best interests to prescribe a full original pack, please document the reason in the patient record.
- There is now a SNOMED code specific to the topiramate ARAF:

Topiramate Pregnancy Prevention Programme Annual Risk Awareness Form completed	2181271000000102
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- Other codes generically applicable to a Pregnancy Prevention Programme are as below and can be applied as per the individual circumstances:

Pregnancy Prevention Programme (PPP) started	1129771000000103
Pregnancy Prevention Programme (PPP) not needed	1129791000000104
Pregnancy Prevention Programme (PPP) declined	1129801000000100
Pregnancy Prevention Programme (PPP) declined by parent	1129821000000109
Pregnancy Prevention Programme (PPP) declined by caregiver	1129811000000103
Pregnancy Prevention Programme (PPP) discontinued	1129841000000102

- Where available, use the [Topiramate Monitoring](#) template from Ardens.
- Further information and educational materials to support the implementation of the new measures is available online via [Topiramate \(Topamax\): introduction of new safety measures, including a Pregnancy Prevention Programme - GOV.UK \(www.gov.uk\)](#)

Patient Information

Patient Guide for [Migraine](#) and [Epilepsy](#) - to be provided to all girls and women of childbearing potential who are started on, or continue to use, topiramate-containing medicines
[Patient Card](#) - to be given by pharmacists to all female patients who are dispensed topiramate to inform them of the risks

Patients may wish to talk to an epilepsy or migraine charity:

- [The Migraine Trust](#) 0808 802 066
- [National Migraine Centre](#) 020 7251 3322
- [Epilepsy Action](#): 0808 800 5050
- [Epilepsy Society](#): 01494 601 400
- [Young Epilepsy](#) 01342 831342

Please continue to record suspected adverse drug reactions to the [Yellow Card scheme](#).

Please continue to record medicine patient safety incidents to [Learning From Patient Safety Events](#)

References

- MHRA drug safety update on [Topiramate \(Topamax\): introduction of new safety measures, including a Pregnancy Prevention Programme - GOV.UK \(www.gov.uk\)](#)

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