NHS Frimley

Topiramate (Topamax): introduction of new safety measures, including a Pregnancy Prevention Programme - a guide for primary care

Topiramate is now contraindicated in pregnancy and in patients of childbearing potential unless the conditions of a Pregnancy Prevention Programme are fulfilled. This follows a review by the MHRA which concluded that the use of topiramate during pregnancy is associated with significant harm to the unborn child. Harms included 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.

- Topiramate should **not** be used;
    - in pregnancy for prophylaxis of migraine
    - in pregnancy for epilepsy unless there is no other suitable treatment
- Topiramate should **not** be used in patients of childbearing potential unless the conditions of the Pregnancy Prevention Programme are fulfilled. This aims to ensure that all patients of childbearing potential;
    - are using highly effective contraception
    - have a pregnancy test to exclude pregnancy before starting topiramate
    - are aware of the risks from use of topiramate

Please refer to the MHRA's advice for prescribers and advice for dispensers and the manufacturer's guides for healthcare professionals (Migraine, Epilepsy).

There is an **Annual Risk Awareness Form** (Migraine, Epilepsy) - for the healthcare professional and the patient (or responsible person) to sign at initiation of treatment with topiramate and at annual treatment reviews. The patient should receive a copy of this form, a copy should be filed in the patient's medical notes, and, if performed in secondary care, a copy sent to the patient's GP

The patient guide for Migraine and Epilepsy - is to be provided to all patients of childbearing potential who are started on, or continue to use, topiramate-containing medicines

Patient Card - to be given by pharmacists to all patients of childbearing potential who are dispensed topiramate to inform them of the risks. Report suspected adverse drug reactions associated with topiramate to the Yellow Card scheme.

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Approved by Frimley Health and Care ICS Medicines Optimisation Board November 2024
Review date November 2026

All patients of childbearing potential currently prescribed topiramate

Identify female patients (aged 13-54) on topiramate
1 Review indication

For migraine

For epilepsy

OR

other off-label indications e.g. psychotropic drug-induced weight gain, neuropathic pain and others

If topiramate was initiated in primary care the GP will be responsible for annual reviews, the annual risk awareness form (ARAF) and making sure the patient is on the Pregnancy Prevention Programme (PPP)

If topiramate was initiated in secondary care and the patient remains under secondary care the annual risk awareness form (ARAF) and Pregnancy Prevention Programme (PPP) will be done at the next annual review by the specialist. If the patient is discharged from follow-up the GP is to decide if they are happy to do the review, if not refer patient to secondary care.

NB for unlicensed indications an epilepsy ARAF should be completed.

2, Review all patients for pregnancy.

If pregnant and on topiramate for epilepsy: Advise not to stop taking topiramate & refer to specialist urgently
If pregnant and on topiramate for migraine prevention: Advise to stop taking topiramate straight away.

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Patients identified as above for reviews by primary care

1. Invite patient in for review. Suggested AccuRx message: ***You are currently prescribed topiramate. A safety review has highlighted it's unsafe if taken during pregnancy. Please read the patient guide. (For epilepsy for prophylaxis of migraine) and book an appointment to discuss. Practice to CHOOSE link appropriate and edit message accordingly.***
2. At review inform the patient of the potential risks of topiramate use in pregnancy and counsel them on treatment options. For alternative options refer to migraine pathway in DXS, Frimley formulary and CKS.
3. If topiramate remains appropriate provide a copy of the Patient Guide (migraine) (epilepsy) to the patient.
4. Assess their potential for pregnancy and discuss the need for them to be on the Pregnancy Prevention Programme.
5. Discuss with them the need to use appropriate highly effective contraception. As topiramate is an enzyme inducer the Faculty of Family Planning and Sexual Health recommend
    - copper IUD or
    - levonorgestrel-releasing IUS, or
    - depot medroxyprogesterone acetate PLUS condoms.

    Use of combined hormonal contraception, progestogen-only pills and the etonogestrel implant is **not recommended**. Contraception should be continued throughout treatment and for at least four weeks after the last dose of topiramate.
6. Complete the Annual Risk Awareness Form with the patient (Migraine) and (Epilepsy) and at each annual review. If there no potential for pregnancy and this is irreversible eg, sterilisation, hysterectomy this should be documented in the patient record and coded appropriately (see below for codes).
7. Consider using the Ardens template: Topiramate Review.
8. Set a diary recall entry for review in 12 months' time and consider including expiry date of the Annual Risk Assessment Form in Patients Notes on Medication screen.
9. There is now a SNOMED code specific to the topiramate ARAF

Topiramate Pregnancy Prevention Programme Annual Risk Awareness Form completed	2181271000000102

Other codes generically applicable to a Pregnancy Prevention Programme are as below and can be applied as per the individual circumstances.

Pregnancy Prevention Programme	*1129761000000105*
Pregnancy Prevention Programme started	*1129771000000103*
Pregnancy Prevention Programme declined	*1129801000000100*
Pregnancy Prevention Programme not needed	*1129791000000104*
Pregnancy Prevention Programme discontinued	1129841000000102
Did not attend Pregnancy Prevention Programme	1129831000000106

Pregnancy Prevention Programme declined by parent	1129821000000109
Pregnancy Prevention Programme declined caregiver	1129811000000103

EMIS Enterprise Searches

Search name: Topiramate in Females of Childbearing Age (11-55 yrs) excl TAH Frimley ICB

Found in East Berkshire reporting folder: MOT>Medicines Safety>Topiramate (2)

Found in Surrey Heath CCG Search>MOCH ANON>Medicines Safety>Topiramate (2)

Found in North East Hants and Farnham CCG>Medicines Management>2024-25>Medicines Safety>Topiramate (2)

Ardens Template

Ardens has produced a template called: Topiramate Review

References:

1. MHRA drug safety update: Topiramate (Topamax): introduction of new safety measures, including a Pregnancy Prevention Programme (June 2024)
2. Faculty of Sexual and Reproductive Healthcare (FSRH) CEU Guidance: Drug interactions with hormonal contraception (May 2022)