

Update for Primary Care: Topiramate (Topamax): New Pregnancy Prevention Programme

Unless the conditions of the New Pregnancy Prevention Programme (PPP) are fulfilled, topiramate is now contraindicated in women of childbearing potential. 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](#)

Information about these risks was publicised prior to introduction of the PPP. An average GP practice within BSW currently has 7 women who may require the PPP.

The PPP aims to ensure that women of childbearing potential:

- Are informed of the risks of topiramate (a Patient Guide for [Epilepsy](#) or [Migraine Prophylaxis](#) is available).
- Are using highly effective contraception (HEC) throughout treatment and for at least 4 weeks after last dose (topiramate is an enzyme inducer that reduces effectiveness of hormonal contraceptives and there are limited options for HEC see [FSRH CEU Guidance: Drug Interactions with Hormonal Contraception \(May 2022\) | FSRH](#) point 9).
- Have an **Annual** Risk Awareness Form (ARAF) completed during a consultation with a *healthcare professional* to document discussion of the risks (there are separate forms for [Epilepsy](#) and [Migraine Prophylaxis](#)).

A Healthcare Professional's Guide to the PPP is available for [Epilepsy](#) and [Migraine Prophylaxis](#).

Topiramate is now classified amber within the local formulary for migraine prophylaxis in women of childbearing potential and for epilepsy. Which means it should not be initiated in primary care for these indications without the advice of a specialist.

This update is summarised in a flow chart on page 4. Arden's have provided tools to support the topiramate PPP see page 6.

Practical Advice for Prescribers

ALL women of childbearing potential CURRENTLY Prescribed Topiramate:

- Identify all women and girls of childbearing potential on topiramate using SystemOne search *Reporting> Clinical Reporting> BSW General Practice> Medicine Optimisation Team > d Safety > Teratogenic Medicine Safety Topiramate: Number of female patients, age 12-55Ys, topiramate on current repeat.*
- Ensure there is a correct read coded indication for topiramate within the clinical record. This will be epilepsy or migraine prophylaxis in most cases.

- Identify any women who are currently pregnant and prescribed topiramate. Topiramate is *contraindicated in pregnancy for prophylaxis of migraine* and should be stopped straight away. *Topiramate for epilepsy should not be stopped abruptly or without specialist input.* Work with local specialist teams as appropriate to the indication.
- Provide those of childbearing potential with the appropriate Patient Guide [Epilepsy](#) or [Migraine Prophylaxis](#) for the PPP. **Advise patients prescribed topiramate for epilepsy not to stop taking topiramate without the advice of a specialist as this will risk worsening epilepsy.** Inform them that as part of the new PPP measures either a healthcare professional from your practice or the specialist neurology service will discuss the PPP with them. This may be at their next review or sooner in some cases.
- Identify, and prioritise for documented discussion, those of childbearing potential who are not using HEC. Please see FSRH guidance which currently recommends limited options of Cu-IUD, LNG-IUS, DMPA plus condoms because topiramate is an enzyme inducer and may reduce the effectiveness of hormonal contraceptives see [FSRH CEU Guidance: Drug Interactions with Hormonal Contraception \(May 2022\) | FSRH](#) point 9. Establish if the decision not to use HEC is an informed choice or an oversight? HEC is the optimal choice. Any decision by the patient not to use should be an *informed* choice and discussions should be documented.
- If you consider there is a compelling reason that there is no potential for pregnancy and the topiramate PPP is not needed, complete “Step 1” on the ARAF. Ensure you add the read code “PPP not needed” (Y2f18) and save the ARAF in the clinical record.

Specific actions for those with an indication of epilepsy:

- **Advise not to stop taking topiramate without the advice of a specialist as this will risk worsening epilepsy.**
- Local neurology services intend to complete the pregnancy prevention programme Annual Risk Awareness Form (ARAF) at the patient's next review.
- Those who have been discharged from regular neurology follow up will need to be referred back into the neurology service via the usual referral system and highlight ‘Topiramate Pregnancy Prevention Programme’ as the reason for referral.
- Those whose are still under the care of neurology for epilepsy but
 - Without clear next follow up or review date, send an email to department with subject “Topiramate PPP” as reason (for RUH Bath email ruh-tr.GiffinSec@nhs.net, GWH Swindon gwh.neurology.secs@nhs.net and Salisbury FT sft.admin.neurology@nhs.net)
 - With upcoming neurology appointments in the next 12 months, no further referral action required from GP

Specific actions for those with an indication of migraine prophylaxis:

- Do NOT routinely refer women of childbearing potential prescribed topiramate for migraine prophylaxis to the neurology/specialist teams.
- Consider if topiramate is still indicated/the best option for the patient. The BSW Primary Care Migraine Pathway can be found here: [Primary-Care-migraine-treatment-pathway_Feb-24-updateFINAL-post-APC.pdf \(bswtogether.org.uk\)](#) (N:B is currently under review to include requirement for topiramate PPP). *Neurology teams can be contacted for advice on treatment options via Cinapsis – Advice and Guidance.*
- If they are currently under follow up with the neurology team or you are unsure due to clinical complexity, please use Cinapsis – Advice and Guidance to establish if the neurology team wish to see the patient.
- For women and girls of childbearing potential who remain on topiramate for migraine prophylaxis who are not managed by neurology, a primary care healthcare professional should ensure the requirements of the PPP are in place and complete the ARAF with the patient to document the discussion about risks, ensuring the ARAF is saved within the patient's clinical records. Read code “**PPP started**” (Y2f16) You may wish to complete the ARAF at the next medication review if you are assured that the patient has been informed of the risks and appropriate highly effective contraception is currently prescribed. **Agree as a practice which Healthcare Professional within the practice is most appropriate to undertake this task.**

Implement a standard operating procedure for recall and assurance that the PPP is in place for all women of childbearing potential prescribed topiramate.

Identify female patient(s) of childbearing potential on topiramate.
 Searches to identify women and girls prescribed topiramate who may require the PPP can be found *Reporting > Clinical Reporting > BSW General Practice > Medicine Optimisation Team > d Safety > Teratogenic Medicine Safety Topiramate: Number of female patients, age 12-55Ys, topiramate on current repeat.*

If currently pregnant and prescribed topiramate.

- Topiramate is *contraindicated in pregnancy for prophylaxis of migraine* and should be stopped straight away.
- Topiramate for epilepsy should not be stopped abruptly or without specialist input. Work with local specialist teams as appropriate to the indication.

Ascertain indication(s) and ensure correctly read coded

Not epilepsy or Migraine prophylaxis? Off label or unlicensed indication?

For epilepsy- Advise not to stop taking topiramate without the advice of a specialist as this will risk worsening epilepsy.

Contact BSW Meds Opt team for advice from the Meds Safety Pharmacists
bswicb.prescribing@nhs.net

For migraine

Review migraine prophylaxis choice and inform the risk of taking topiramate by using Patient Guide [Migraine Prophylaxis](#)

Provide Patient Guide [Epilepsy](#) . Inform patient that as part of the new PPP measures HCPs will be in contact to organise a review to discuss their treatment and address their questions

Obtain informed consent to continue with prophylaxis.

Discharged/Not known to neurology specialist

Under active follow up by neurology specialist

Complete the ARAF with patient (or responsible person) and document in clinical record

Initiate referral via Ardens and highlight "Topiramate Pregnancy Prevention Programme" as referral reason, specialist to complete the ARAF

- Without clear next follow up or review date
- >> Send email to department and highlight subject "Topiramate Pregnancy Prevention Programme"
- With upcoming neurology appointments in the next 12 months
- >> No further referral action required from GP

If PPP not applicable

If PPP applicable

If PPP applicable

- Complete ARAF Step 1 ONCE only
- Document the compelling reason indicates no potential for pregnancy
- Code "PPP not needed" (Y2f18)

- Complete ARAF Step 1 & 2
- Code "PPP started" (Y2f16)
- Organise annual review and complete ARAF

For women and girls of childbearing potential who remain on topiramate and if PPP is applicable:
 Discuss with patient(s) the need to use **highly effective contraception*** throughout treatment and for at least four weeks after the last dose of topiramate. See guidance from The Faculty of Sexual and Reproductive Healthcare (FSRH) on potential drug interactions with hormonal contraceptives.
 * Topiramate is an enzyme inducer that reduces effectiveness of hormonal contraceptives and there are limited options for HEC, see [FSRH CEU Guidance: Drug Interactions with Hormonal Contraception \(May 2022\)](#) | FSRH point 9

Implement a standard operating procedure for recall and assurance that the PPP is in place for all women of childbearing potential prescribed topiramate.

Arden's Resources

Report found in Prescribing | Alerts > Neurology:

The screenshot shows the 'Neurology' section of the Arden's Resources interface. A list of alerts is displayed, with one alert highlighted in blue:

- On modafinil | Review results as BP >160/100
- On riluzole | Abnormal blood result (ALT >135, Neu <1.5 or WCC <2.5)
- On tolcapone | Review as ALT >45
- On topiramate | ?For Pregnancy Prevention Programme as childbearing potential + none in last 1y**
- On valproate | Abnormal blood result (Hb <120, Pit <150 or ALT >135)
- On valproate | Review as child bearing potential + no ARAF in last 1y
- On valproate | Review as child bearing potential + no PPP in last 1y

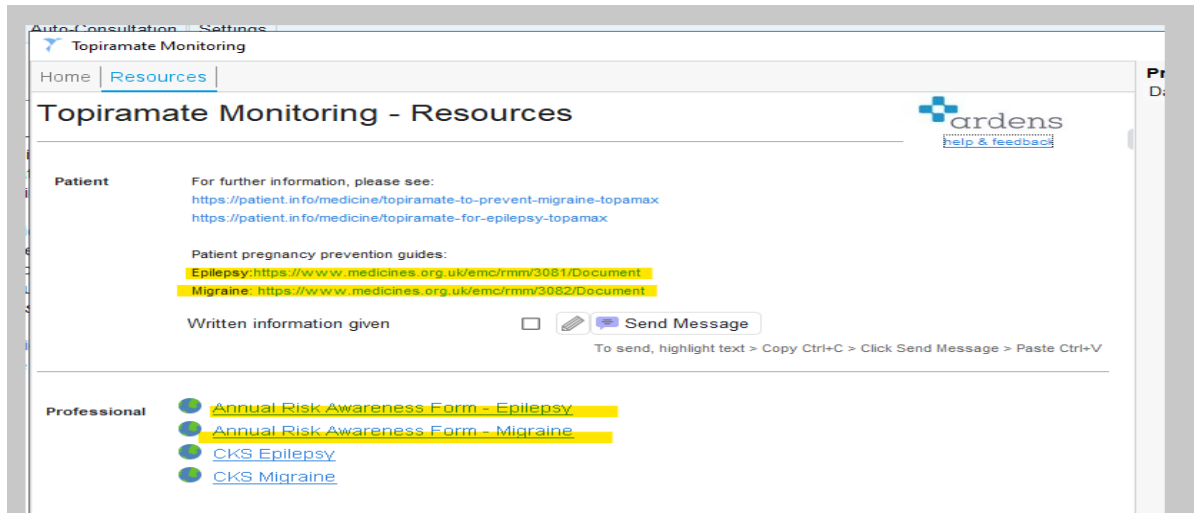
Updates to the monitoring template including newest MHRA alert link, information about highly effective contraception (as per FSRH- enzyme inducing medication and hormonal contraception), new drop down to record PPP:

The screenshot shows the 'Topiramate Monitoring' template. The 'Pregnancy Prevention' dropdown menu is open, displaying a list of options:

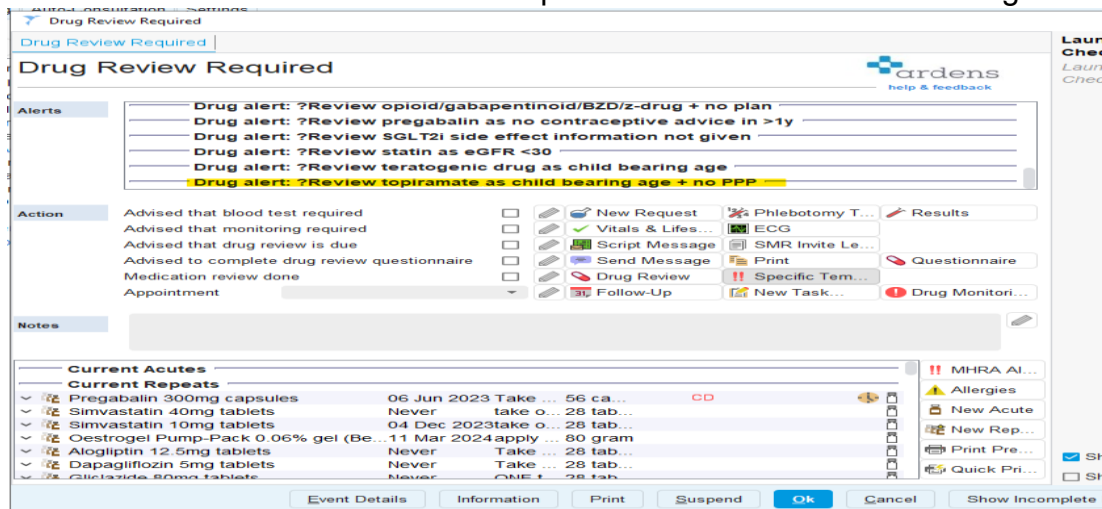
- Pregnancy prevention programme (Y20ab) (SNOMED: 1129761000000105)
- Pregnancy prevention programme declined (Y217) (SNOMED: 1129801000000100)
- Pregnancy prevention programme declined caregiver (Y21f1c) (SNOMED: 1129811000000103)
- Pregnancy prevention programme declined by parent (Y21f1b) (SNOMED: 1129821000000109)
- Pregnancy prevention programme discontinued (Y21f19) (SNOMED: 1129841000000102)
- Pregnancy prevention programme not needed (Y21f18) (SNOMED: 1129791000000104)
- Pregnancy prevention programme started (Y21f16) (SNOMED: 1129771000000103)
- Did not attend pregnancy prevention programme (Y21f1a) (SNOMED: 1129831000000106)

The dropdown menu also includes a link to 'Use highly effective contraception - BDI/MS/DMPA + barrier - as increased risk of congenital malformation + fetal growth restriction'.

Resources page includes links to the patient pregnancy prevention guides for epilepsy and migraine and links to the professional resources, ARAF for epilepsy and Migraine:



Associated alert that will show on the patient's home screen that a Drug review is required:

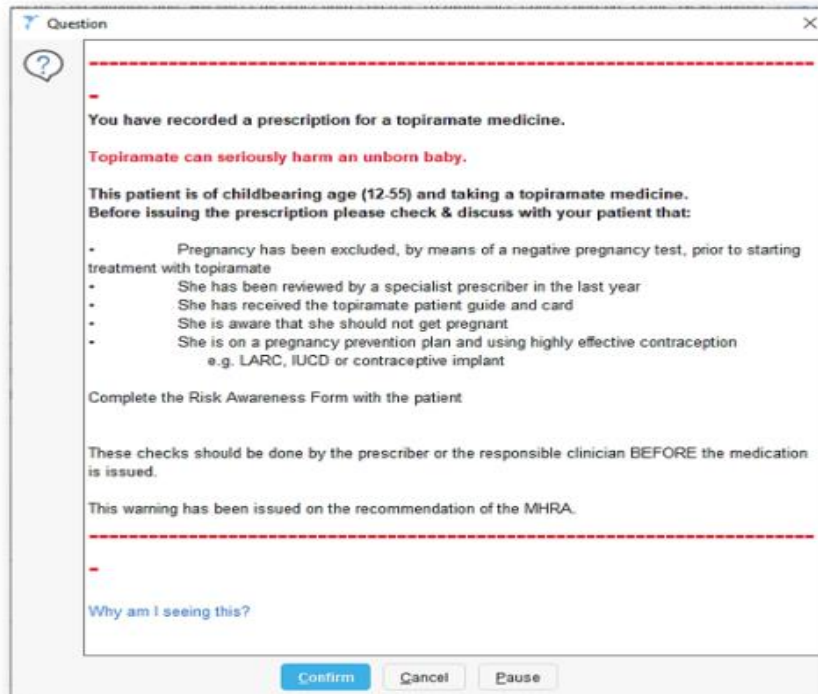


SystemOne Alert

1. Pop-up Alert

SystemOne have published a nationwide pop-up following the updated MHRA alert. This alert will pop-up in the following circumstances:

- When a topiramate medicines is prescribed as an acute or repeat
- When a repeat template for topiramate medicine is issued
- When a patient who has a current repeat topiramate medicine prescription record is retrieved



The screenshot shows a pop-up window titled "Question" with a question mark icon in the top left corner. The window contains the following text:

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You have recorded a prescription for a topiramate medicine.

Topiramate can seriously harm an unborn baby.

This patient is of childbearing age (12-55) and taking a topiramate medicine.
Before issuing the prescription please check & discuss with your patient that:

- Pregnancy has been excluded, by means of a negative pregnancy test, prior to starting treatment with topiramate
- She has been reviewed by a specialist prescriber in the last year
- She has received the topiramate patient guide and card
- She is aware that she should not get pregnant
- She is on a pregnancy prevention plan and using highly effective contraception e.g. LARC, IUCD or contraceptive implant

Complete the Risk Awareness Form with the patient

These checks should be done by the prescriber or the responsible clinician BEFORE the medication is issued.

This warning has been issued on the recommendation of the MHRA.

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[Why am I seeing this?](#)

At the bottom of the window are three buttons: "Confirm" (highlighted in blue), "Cancel", and "Pause".