

**July 2024**

## **General Practice Actions for The Safe Use of Topiramate in NEL**

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.

### **MHRA UPDATES- NEW SAFETY MEASURES – PREGNANCY PREVENTION PROGRAMME FOR TOPIRAMATE PRESCRIBING:**

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

To strengthen the governance relating to the safe use of topiramate, the North East London Teratogenic Medicines Safety Improvement group will provide oversight to support providers (primary and secondary care, mental health trusts) with the implementation of these new safety measures.

OptimiseRx messages have been updated to reflect this alert. Please review prescriptions and patients in line with the messages

#### **Action for General Practices:**

- Do NOT initiate Topiramate unless this is normally requested by the relevant specialist in neurology, mental health or migraine clinics.
- Initiate an EMIS (or SystmOne) search to identify patients in your practice who are 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.
- To minimise additional pressure for appointments in 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.
- Patients who are not recorded as under the care of a local specialist should be referred to the appropriate specialist using existing referral pathways.
- Ensure the **Pregnancy Prevention Programme** and a **topiramate pregnancy Risk Awareness Form (RAF)** has been completed for all women and girls of child-bearing potential on topiramate.
- Ensure existing women and girls of childbearing potential use a highly effective form of contraception and for at least four weeks after the last dose of topiramate. Guidance on highly effective contraception is available at <https://bnf.nice.org.uk/treatment-summaries/contraceptives-hormonal/>
- Provide a copy of the Patient Guide for [Migraine or Epilepsy](#) to all eligible patients (or their guardian / responsible person) who continue to use topiramate-containing medicines.
- 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.
- 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 \(www.gov.uk\)](#)
- Please continue to report suspected adverse drug reactions to the [Yellow Card scheme](#).
- Please continue to report medicines safety incidents to [Learning From Patient Safety Events](#)