

Prescribing Tip for Information

Topiramate safety review

Topiramate is an antiepileptic used

- Alone to treat seizures in adults and children aged older than 6 years
- With other medicines to treat seizures in adults and children aged 2 years or older
- To prevent migraine headaches in adults **after consideration of possible alternative treatment options**

In January 2021 the MHRA updated [its' advice](#) on the use of antiepileptic drugs in pregnancy following a comprehensive national review by the Commission on Human Medicines (CHM) of the safety of antiepileptic drugs in pregnancy. **Amongst other findings the review highlighted**

- **An increased risk of major congenital malformations associated with carbamazepine, phenobarbital, phenytoin and topiramate use during pregnancy.**
- **An increased risk of fetal growth restriction associated with phenobarbital, topiramate and zonisamide use during pregnancy.**

General advice from the MHRA for prescribers included

- At initiation and as part of the recommended annual review for patients with epilepsy, specialists should discuss with women the risks associated with antiepileptic drugs and with untreated epilepsy during pregnancy and review their treatment according to their clinical condition and circumstances – a [safety information leaflet](#) has been produced to assist with this discussion.
- Urgently refer women who are planning to become pregnant for specialist advice on their antiepileptic treatment.
- All women using antiepileptic drugs who are planning to become pregnant should be offered 5mg per day of folic acid before any possibility of pregnancy.

In May 2022 **a large observational study** reported that prenatal exposure to topiramate is associated with an increased risk of autism spectrum disorder, intellectual disability and neurodevelopmental disorders. The CHM have subsequently considered the findings of the study and have advised that it provides robust evidence of an association.

A [new safety review](#) is now being undertaken to evaluate the benefits and risk of use of topiramate in women of child bearing potential. **Whilst this review is undertaken it is important to continue to counsel patients of childbearing potential on the known and emerging risks of topiramate for an unborn baby.**

Specific advice in relation to topiramate

- **Do not prescribe topiramate during pregnancy for migraine prophylaxis.** For migraine prophylaxis, topiramate can be withdrawn in pregnancy by an appropriate prescriber but alternative treatments should be considered.
- **Anyone who is able to get pregnant should have a pregnancy test before they start topiramate treatment.**
- **Counsel patients on the importance of avoiding pregnancy during topiramate use** due to these emerging data and also the established increased risks of major congenital malformations and fetal growth restriction in babies exposed to topiramate in-utero.
- **Ensure any patients of childbearing potential know to use highly effective contraception throughout treatment with topiramate.** Topiramate may reduce the effectiveness of steroidal contraceptives, including oral contraceptives, therefore consider alternative or concomitant methods (see [Advice on contraceptive interactions](#)).
- **For epilepsy, urgently refer anyone on topiramate who is planning a pregnancy or who is pregnant for specialist advice on their antiepileptic treatment.**

To contact the Medicines Optimisation Team please phone 01772 214302

If you have any suggestions for future topics to cover in our prescribing tips please contact Nicola.schaffel@nhs.net

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