

Medicines Optimisation MHRA Drug Safety Update – July 2022

The latest MHRA Drug Safety Updates can be accessed at <https://www.gov.uk/drug-safety-update> . This includes links to alerts, recalls and safety information and to the monthly Drug Safety Update PDF newsletter.

The July 2022 Drug Safety Update includes:

- [Topiramate and known harms if used in pregnancy](#)
- [New national safety review of topiramate](#)
- [Further details on the findings of the new study](#)
- [Topiramate and current pregnancy prevention requirements](#)
 - [Advice on contraceptive interactions](#)
- [Valproate: current strict restrictions](#)
- [Medicines and Pregnancy Registry](#)
- [Report suspected reactions on a Yellow Card](#)

Summary of MHRA advice:

“Advice for healthcare professionals:

- we have started a new safety review to assess the benefits and risks of topiramate and to consider whether further measures are required to reduce the risk of harm associated with topiramate use during pregnancy
- the new safety review was triggered by a large [observational study](#) reporting that prenatal exposure to topiramate is associated with an increased risk of autism spectrum disorders, intellectual disability, and neurodevelopmental disorders

- of the antiepileptic medicines reviewed for use in pregnancy, lamotrigine and levetiracetam continue to be considered the safer for the baby since they were not associated with an increased risk of birth defects – see [advice following comprehensive safety review of antiepileptic drugs in pregnancy](#)
- it remains vital that the strict restrictions for valproate prescribing in women and girls of childbearing potential are followed given the known significant risks if valproate is used in pregnancy (see [dedicated section below](#))

Reminder of current advice for topiramate:

- do not prescribe topiramate during pregnancy for migraine prophylaxis
- ensure any patients of childbearing potential know to use highly effective contraception throughout treatment with topiramate
- 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
- topiramate may reduce the effectiveness of steroidal contraceptives, including oral contraceptives, therefore consider alternative or concomitant methods (see section on [Advice on contraceptive interactions in the article](#))
- for migraine prophylaxis, topiramate can be withdrawn in pregnancy by an appropriate prescriber but alternative treatments should be considered
- for epilepsy, urgently refer anyone on topiramate who is planning a pregnancy or who is pregnant for specialist advice on their antiepileptic treatment

Advice to provide to patients:

- do not stop taking topiramate without first discussing it with your doctor
- topiramate can harm the way an unborn baby grows and develops during pregnancy – see advice on [epilepsy medicines and pregnancy](#)
- a new study has also linked topiramate to an increased risk of autism spectrum disorders and intellectual disabilities (effects on learning and development) in children exposed to it during pregnancy

- the MHRA and its independent experts are investigating whether there needs to be changes to how topiramate can be used in UK patients – we will communicate the outcomes of this review once it has concluded
- if you are taking topiramate for epilepsy and are planning a pregnancy, urgently talk to your doctor for a specialist review – there are other epilepsy medicines that are not associated with an increased risk of birth defects in pregnancy
- if you are taking topiramate for migraine and planning a pregnancy, talk to your prescriber about alternative treatments that can be used in pregnancy as soon as possible
- anyone who is able to get pregnant should have a pregnancy test before they start topiramate treatment and use effective contraception while taking topiramate
- topiramate can reduce the effectiveness of hormonal contraception in preventing unplanned pregnancy – talk to a healthcare professional about the best contraception for you while you are taking topiramate”

[COVID-19 vaccines and medicines: updates for July 2022](#)

[Letters and medicine recalls sent to healthcare professionals in June 2022](#)

The MHRA Central Alerting System alerts can be accessed at <https://www.cas.mhra.gov.uk/Home.aspx> .

National Patient Safety Alerts can be accessed at <https://www.england.nhs.uk/patient-safety/patient-safety-alerts/> .

We are reviewing our response to MHRA and National Patient Safety Alerts to include local advice. In the meantime we have included a summary of the MHRA Drug Safety Update.

This update is prepared by the NHS Kent and Medway Medicines Optimisation Team.