

Safety review of epilepsy medicines in pregnancy – women who may become pregnant urged to discuss treatment options with their doctor

Lamotrigine (Lamictal) and levetiracetam (Keppra) have been found to be safer than other antiepileptic drugs in pregnancy. The MHRA advises patients not to stop taking their current medicines without first discussing it with a healthcare professional.

The [review](#) by the Medicines and Healthcare products Regulatory Agency examined safety data for risks of major birth defects or abnormalities and concerns with the child's development including learning and thinking abilities for other key antiepileptic drugs. It found that a number of these epilepsy medicines may be associated with some increased risks in pregnancy.

Valproate (Epilim) is already known to be seriously harmful if taken in pregnancy and should only be prescribed to a woman if a pregnancy prevention plan is in place. Importantly, two antiepileptic medicines in particular, lamotrigine (Lamictal) and levetiracetam (Keppra), have both been found to be safer than other antiepileptic drugs in pregnancy. The MHRA advises patients never to stop taking their current epilepsy medicines without first discussing it with a healthcare professional.

Dr Sarah Branch, Director of MHRA's Vigilance and Risk Management of Medicines Division said:

Patient safety is our highest priority, and we are committed to making sure women are aware of the risks of taking certain epilepsy medicines during pregnancy, particularly valproate.

We have shared this important review with doctor and nurses so they can use it to inform discussions with their patients.

If a woman is planning to become pregnant, and is taking a medicine for epilepsy, even if this is some time in the future, it is very important that she should discuss with a healthcare professional the right treatment for her, taking into account the results of this review.

It is vitally important that women don't ever stop taking any epilepsy medicine without discussing it first with a healthcare professional.

Louise Cousins, Director of External Affairs at [Epilepsy Action](#) said:

We're pleased to see that this review has taken place. This information has been provided to doctors and nurses, so that women can be made aware and supported to make informed decisions about their care and treatment.

No woman or girl should be taking an anti-epileptic medication without them, or their family, being aware of the risks as the consequences can be devastating.

Dr Jo Mountfield, Consultant Obstetrician and Vice President at the [Royal College of Obstetricians and Gynaecologists](#) said:

We welcome the MHRA's safety review of epilepsy medicines in pregnancy and any associated risks.

It's important to discuss with your doctor if you are considering stopping medication for long-term conditions completely or altering the dose as this can pose a serious risk to your health.

We advise that women with epilepsy should seek advice and information from their doctor pre-conception as well as throughout their pregnancy. This will help ensure women can make well informed decisions about planning their pregnancy and any concerns they have about their medication.

Paul Chrisp, Director of the Centre for Guidelines at [NICE](#), said:

NICE welcomes this move from MHRA to ensure women are fully aware of the risks of taking certain epilepsy medicines during pregnancy. We've already made changes to our guidelines to reflect MHRA's earlier advice about the use of sodium valproate.

It's important that everyone affected by these latest changes is made aware of them as soon as possible. We're therefore taking steps to review our guidelines where these medicines are recommended, including the assessment and management of bipolar disorder, depression in adults, and antenatal and postnatal mental health to reflect this important advice.

Our guideline on the diagnosis and management of epilepsies is currently being updated as part of our normal review cycle; in the meantime we will ensure the new advice is clearly signalled within the existing guideline.

Antiepileptic drugs are crucial to control seizures and other epilepsy symptoms. Untreated epilepsy can cause harm to both mother and unborn baby.

The review on the use of epilepsy medicines in pregnancy was carried out by the Commission on Human Medicines (CHM) following earlier reviews of the antiepileptic medicine, valproate, which is known to be harmful if taken during pregnancy.

The MHRA is asking clinicians to use the review's findings to discuss the potential risks to the baby associated with epilepsy medicines and untreated epilepsy during pregnancy, and to review patients' treatment according to their clinical condition and circumstances. The MHRA has produced a safety information leaflet to help with this discussion.

The MHRA has a [Valproate guidance page](#) with more information about the risks and regulatory action taken to date.

Notes to Editor

1. The [Medicines and Healthcare products Regulatory Agency](#) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.
2. The MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the [National Institute for Biological Standards and Control \(NIBSC\)](#) and the [Clinical Practice Research Datalink \(CPRD\)](#). The MHRA is an executive agency of the Department of Health and Social Care.
3. [The Commission on Human Medicines \(CHM\)](#) advises ministers on the safety, efficacy and quality of medicinal products. The CHM is an advisory non-departmental public body, sponsored by the [Department of Health and Social Care](#).
4. The review was carried out by the Commission on Human Medicines (CHM) following earlier reviews of the antiepileptic medicine, valproate, which is known to be harmful if taken during pregnancy. If valproate is taken during pregnancy, up to 4 in 10 babies are at risk of developmental disorders and approximately 1 in 10 are at risk of birth abnormalities (birth defects). For this reason, in 2018 the MHRA introduced the valproate [pregnancy prevention programme](#) and is committed to reducing the use of valproate in pregnancy to an absolute minimum. The review found that other epilepsy medicines may be associated with some increased risks of birth abnormalities or other effects on the baby. However, no epilepsy medicines reviewed are thought to have a risk greater than that of valproate.
5. [Drug Safety Update](#), [Public Assessment Report](#) and [safety leaflet](#).