Department of Health & Social Care

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Chief Medical Officer Alert

Valproate contraindicated in women of childbearing potential unless there is a Pregnancy Prevention Programme

Actions

1. GPs should identify all relevant women and girls on valproate in their practice, check that they are on effective contraception as appropriate, and refer them for specialist review
2. Specialists should review treatment and, if valproate is the only suitable treatment, ensure an acknowledgment of risk form is signed by you and the patient

Action required by: all providers of NHS funded care.

Dear colleague,

Use of valproate in pregnancy is associated with a 40% risk of persistent neurodevelopmental disorders and a 10% risk of physical birth defects. Despite repeated communications on this risk, it is estimated that 400 women in the UK took valproate during pregnancy in 2016.

Following a review of the situation across the EU, **valproate is now contraindicated in women of childbearing potential unless they meet the conditions of a Pregnancy Prevention Programme**, which will include a risk acknowledgement form to be completed and signed by the specialist prescriber and the patient in a review at least once a year. Educational materials to support the implementation of the Pregnancy Prevention Programme will be sent to healthcare professionals by post in the coming weeks. These materials will include a Guide for Patients to explain the new prescribing restrictions, which should be provided to all girls and women of childbearing potential who start treatment with valproate or who are already on treatment.

I now expect the healthcare system to make changes to ensure that girls and women of childbearing potential are only taking valproate if there is no other suitable treatment, that they know about the risks in pregnancy, and that, where appropriate, they are on effective contraception.

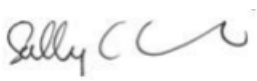
There are approximately 27,000 women of childbearing age receiving prescriptions for valproate in primary care in the UK. GPs should identify all relevant women and girls on valproate in their practice, check that they are on effective contraception as appropriate, and refer them for specialist review unless they have already had a review in the last year.

Specialist prescribers should assess whether treatment with valproate is necessary for any women or girl of childbearing potential referred to them (ie, there is no suitable alternative treatment). If continued treatment is necessary, the woman or girl must be enrolled on the Pregnancy Prevention Programme, be on effective contraception, and understand the need to avoid pregnancy.

The Medicines and Healthcare products Regulatory Agency has been working with professional bodies and the health system to bring together a package of measures to support healthcare professionals in implementing this change. NICE has updated its guidelines which mention valproate. GP electronic system providers have provided a search and audit function to facilitate the identification of women of childbearing age on valproate and are updating the alerts for valproate.

Valproate remains an appropriate treatment for some patients and it is vital that these measures are implemented in a way that does not cause alarm. We will be monitoring the effectiveness of the new measures in changing prescribing of valproate to women of childbearing age and in preventing pregnancies from being exposed to valproate. This data will be published and there will be follow up to ensure progress is being made. For more information, including details on the new regulatory measures, see the MHRA website.

Thank you for your support in implementing this.
Yours ever,



Professor Dame Sally Davies
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