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For people who have hearing loss
Minicom 01908 243924**Memo – Patient Safety Alert: Resources to support the safety of girls and women who are being treated with valproate.**To: All wards and clinical areas
From: Pharmacy Department
Date: April 13, 2017**Background**

NHS Improvement has issued a [Patient Safety Alert](#) regarding the use of valproate in girls and women and the resources to support safety.

Valproate, also known as valproic acid (brand names include Epilim and Depakote), is an effective medication used to treat epilepsy and bipolar disorder. Although unlicensed for treatment of other conditions in the UK, 'off-label' use for migraine or chronic pain has also been reported.

In girls and women of childbearing potential, valproate should be initiated and supervised by a specialist and **only** when other medications have not been tolerated or have been found to be ineffective. Unborn babies exposed to valproate during pregnancy are at very high risk (30-40 in every 100) of neurodevelopment disability - such as lower intelligence and autistic spectrum disorders, and also at risk (10 in every 100) of other birth defects.

In 2015 the MHRA published the valproate [toolkit](#), providing a set of resources for patients, GPs, pharmacists and specialists. This was added to in February 2016 and April 2017. These resources emphasise the need to avoid the use of valproate in girls and women of childbearing potential; warn women of the very high risks to the unborn child of valproate in pregnancy; and emphasise the need for effective contraception planning and specialist oversight of changes to medication when planning a pregnancy, as abrupt changes to medication can be harmful.

Action

- Valproate should not be prescribed to female children, female adolescents, women of childbearing potential or pregnant women unless other treatments are ineffective or not tolerated.
- If valproate treatment is started, it must be supervised by a doctor experienced in managing epilepsy or bipolar disorder.
- Carefully balance the benefits of valproate treatment against the risks when prescribing valproate for the first time, at routine treatment reviews, when a female child reaches puberty and when a woman plans a pregnancy or becomes pregnant.
- Female patients should be informed of and understand:
 - The risks associated with valproate during pregnancy;
 - The need to use effective contraception;
 - The need for regular review of treatment;
 - The need to rapidly consult if she is planning a pregnancy or becomes pregnant.

- Specialists (neurologists, psychiatrists and paediatricians) to follow the resources in the toolkit to help manage and minimise the risks and ensure processes are in place to allow these requirements to be met.
- Paediatricians should also refer parents or carers to the Royal College of Paediatrics and Child Health information about valproate (via <http://www.medicinesforchildren.org.uk/sodium-valproate-preventing-seizures>).
- Pharmacists should give a [patient card](#) whenever valproate is dispensed for a woman of childbearing potential or girl with encouragement to read the card and enter the patient's name and date to reinforce accountability to consider the information it contains.
- Please continue to report any suspected side effects to valproate or any other medicine on a [Yellow Card](#) (see also [guidance on reporting side effects experienced by the woman or child to medicines taken during pregnancy](#)).

For further advice, please contact Medicines Information on Ext 85738.

References

- Patient Safety Alert. Resources to support the safety of girls and women who are being treated with valproate. Accessed via https://improvement.nhs.uk/uploads/documents/Patient_Safety_Alert_-_Resources_to_support_safe_use_of_valproate.pdf on April 13th 2017.
- MHRA Letter 8 February 2016. Valproate and risk of abnormal pregnancy outcomes: new communication materials. Accessed via <https://www.gov.uk/drug-safety-update/valproate-and-of-risk-of-abnormal-pregnancy-outcomes-new-communication-materials>