Cheshire and Wirral Partnership NHS
NHS Foundation Trust

Communications Bulletin

October 2016

What this bulletin is about**:**	**Medicine Alert:** Medicines containing valproic acid: Risk of abnormal pregnancy outcomes
Who it is being sent to:	All ward clinical staff, all doctors, all community team staff, all nurse prescribers, CWP pharmacy team and Lloyds pharmacy Team
Action required by you:	Please cascade to relevant staff in your area or staff without regular access to email as soon as possible and action the message below

Medicine alert: Medicines containing valproic acid: Risk of abnormal pregnancy outcomes CWP audit shows that prescribing of valproate in females of childbearing age is still occuring

Background

Further to a CWP Medicine Alert issued in June 2015, a recent CWP-POMH audit has shown that 27% of patients prescribed valproate of the sample reviewed, were women under the age of 50, compared with 9% of the national sample. A significant proportion of the sample audited had no evidence of documentation of the requirements for appropriate patient counselling.

VALPROATE (Sodium Valproate, Valproic Acid, Epilim®, Epilim Chrono®, Epilim Chronosphere® Epival®, Depakote®, Episenta®, Convulex®) contains valproic acid an active ingredient with known teratogenic effects which may result in congenital malformations. Available data also show that in utero exposure to valproate can be associated with an increased risk of developmental disorders.

Summary:

- 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.
- Children exposed in utero to valproate are at a high risk of serious developmental disorders (in up to 30-40% of cases) and congenital malformations (in approximately 10% of cases)
- If valproate is prescribed for a woman of childbearing age, there should be documented evidence in the patient's notes that the patient has been 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

The risks are outlined below:

1. CONGENITAL MALFORMATIONS

- Available data shows the risk is dose dependent. The risk is greatest at higher doses (above 1g daily).
- A threshold dose below which no risk exists cannot be established based on available data.
- The most common types of malformations include neural tube defects, facial dysmorphism, cleft lip and palate, craniostenosis, cardiac, renal and urogenital defects, limb defects (including bilateral aplasia of the radius), and multiple anomalies involving various body systems.

2. DEVELOPMENTAL DISORDERS

- Exposure to valproate in utero can have adverse effects on mental and physical development of the exposed children. The risk seems to be dose-dependent but a threshold dose below which no risk exists, cannot be established based on available data.
- The exact gestational period of risk for these effects is uncertain and the possibility of a risk throughout the entire pregnancy cannot be excluded.
- Available data shows that children exposed to valproate in utero are at increased risk of autistic spectrum disorder (approximately three-fold) and childhood autism (approximately five-fold) compared with the general study population.
- One study suggests that children exposed to valproate in utero may be more likely to develop symptoms of Attention Deficit Hyperactivity Disorder (ADHD).

What does this mean for our staff?

1. All clinicians considering prescribing valproate should read the healthcare professional booklet which gives:
   - a comprehensive overview of the risks of valproate in females of childbearing potential and during pregnancy,
   - points to consider and steps to take when deciding to treat women of childbearing potential and girls with valproate.

2. Whenever you conclude it necessary to treat or continue treating a woman of childbearing potential or girl with valproate, use the checklist to check that you have given her all the necessary information and that she has fully understood it. Add the completed checklist to her medical records as a permanent record of your discussion.

3. When considering treating females (adults or children) of childbearing potential with valproate, give her or her carer the valproate patient guide and ensure that she understands the information it contains.

4. Please review all girls and women of childbearing potential, currently taking valproate noting the points 1-3 above. The HQIP team are currently working with Information to obtain a list of patients at risk, and this will be communicated to you shortly.

Source: https://www.gov.uk/drug-safety-update/valproate-and-of-risk-of-abnormal-pregnancy-outcomes-new-communication-materials

Please find attached the results from the POMH-UK audit.

Summary of results for circulating with bri

POMH-UK Topic15a Trust 087.pptx

For further information/advice please contact the clinical pharmacy team (contact numbers are found on the medicines and pharmacy services intranet page) http://nww.cwp.nhs.uk/TeamCentre/Pharmacy/Lists/Contacts/Default.aspx

Regards

CWP POMH Steering Group

Dr Amrith Shetty, Consultant Psychiatrist
Dr Taj Nathan, Consultant Psychiatrist
Jasmeen Islam, Deputy Chief Pharmacist
Dr Gagandeep Singh, Consultant Psychiatrist
Kate Baxter, HQI Lead

Chair - Perinatal Mental Health Clinical Network

Dr Tania Stanway, Consultant Psychiatrist