

**To: All Medical and Non-Medical Prescribers**  
**CC: All Nursing and Pharmacy Staff**

**May 2016**

## **Notification Regarding Valproate and Females of Childbearing Potential: Patient Consent and Provision of Information**

The MHRA have communicated the risks to healthcare professionals that are associated with prescribing valproate to females of childbearing potential on a number of occasions. Most recently in February 2016, a Drug Safety Update was issued which can be accessed at:

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

This reiterates the risks that exist when prescribing valproate to females of childbearing potential and the precautions that must be taken when doing so. In summary:

- Valproate is teratogenic when taken during pregnancy. Congenital malformations occur at a rate of 10% and include neural tube defects, facial dysmorphism, cleft lip and palate, cardiac, renal, urogenital and limb defects. Developmental disorders occur at a rate of 30-40% and include being late in learning to walk and talk, being of lower intelligence, having poor speech and language skills, memory problems and are more likely to have autism and develop symptoms of ADHD.
- Valproate should not be prescribed to females of childbearing potential or in pregnancy unless other treatments are ineffective or not tolerated.
- If the decision is made to prescribe valproate to a female of childbearing potential you must ensure that the patient is informed about and understands the risks associated with valproate during pregnancy, the need to use effective contraception, and the need to rapidly consult the prescriber if she is planning to become pregnant or becomes pregnant.

The MHRA has produced a series of resources to support healthcare professionals with the implementation of this Drug Safety Alert. Resources include:

- An information booklet for healthcare professionals
- A patient information booklet
- A patient alert card
- A checklist to be completed by the prescriber with the patient

These resources can be downloaded and printed from the above web link, alternatively printed copies can be ordered from: [UK-Medicalinformation@sanofi.com](mailto:UK-Medicalinformation@sanofi.com)

Following discussion at the trust Medicines Optimisation Committee it has been agreed that the information and resources contained within this Drug Safety Alert will be adopted and implemented in full throughout SSSFT.

Medical, nursing and pharmacy staff must ensure that they understand the risks associated with the use of valproate in females of childbearing potential.

In females of childbearing potential, valproate must only be initiated by a specialist experienced in the treatment of bipolar disorder or epilepsy when other treatments are ineffective or not tolerated and treatment should be regularly reviewed. If valproate is being prescribed for an off licence indication the requirements of this Drug Safety Alert still apply.

The patient/prescriber checklist should be discussed and completed, signed and dated by both the prescriber and the patient if treatment with valproate in a female of childbearing potential is to commence/continue. This must be uploaded into RiO as a permanent record of your discussion with the patient.

The patient information book must be issued to the patient for them to keep.

SSSFT dispensaries will issue an alert card when they dispense discharge medication containing valproate to females of childbearing potential.

If you have any queries regarding this Drug Safety Update or its implementation please contact your ward/team pharmacist via the SSSFT Pharmacy & Medicines Optimisation Department.

Kind Regards

A handwritten signature in black ink, appearing to read 'Erica Young', written over a faint, illegible stamp or background.

Erica Young  
Lead Clinical Pharmacist

Approved by:

A handwritten signature in black ink, appearing to read 'Abid Khan', written in a cursive style.

Dr Abid Khan  
Consultant Psychiatrist  
Chair of Medicines Optimisation Committee  
Medical Director