Valproate Toolkit to address Reproductive Risks

Please follow the links below from the Medicines and Healthcare products Regulatory Agency (MHRA) for information about the reproductive risks of taking valproate medicines and the measures in place to reduce potential harm.

Background

- Information about valproate

- Female patients

- Male patients

Information for Healthcare Professionals:

- Healthcare professionals Guide: Provides updated information to support management in relation to the risks of valproate in pregnancy and the risks for male patients. This includes the new conditions for valproate prescribing and key points for patient discussions including but not limited to your role as a:

o Specialist prescriber

o General Practitioner

o Gynaecologist/Obstetrician/Midwife/nurse

o Pharmacist

- Three infographics describe circumstances where review by two specialists may be required:

  - for female patients under 55 years old
  - for male patients under 55 years old newly starting valproate
  - for male and female patients 55 years and older (valproate can be prescribed in accordance with standard clinical practice by a single prescriber)

- Annual Risk Acknowledgement Form: For female patients under 55 years starting valproate and at annual review to ensure requirements in the Pregnancy Prevention Plan are followed. This form must be used to support and record the discussion between the patient and specialist prescriber on the risks associated with valproate in pregnancy and to record the decision of the countersigning specialist. At subsequent annual reviews only one specialist is required.

- Male Risk Acknowledgement Form: Used to support and record the discussion between the patient and specialist prescriber of the risks associated with valproate in males under 55 years when starting treatment with valproate and to

record the decision of the countersigning specialist. This is only to be completed at initiation of valproate.

- Pharmacy Poster: Provides important actions for pharmacists dispensing valproate to patients.

Information for patients

- Patient guides for female and male patients: Provides those taking valproate (or their parent, caregiver, or responsible person) with information on the risks of valproate in pregnancy and the risks to male patients and what they need to do.
- Patient Card: Provides key information for female patients receiving valproate on contraception and pregnancy prevention, and precautionary advice for men and their female partner to use effective contraception.
- Patient support networks

Clinical resources

The following resources are available to support healthcare professionals understand their clinical responsibilities for valproate:

- Overview | Epilepsies in children, young people and adults | Guidance | NICE
- Association of British Neurologists – ABN guidelines for valproate prescribing in adult (16 or over) neurology
- British Paediatric Neurology Association (BPNA) and the Royal College of Paediatrics and Child Health (RCPCH) – Joint guidance to provide recommendations about the use of valproate in female patients under 18 years of age
- BPNA, OPEN UK, RCPCH prescribing guidance document
- Monitoring impact: MHRA have launched a Medicines and Pregnancy Registry in partnership with NHS England (formerly NHS Digital). This provides six-monthly reports to help monitor the effectiveness of the valproate pregnancy prevention plan.