



New MHRA valproate safety regulations from January 2024 -system holding statement.

Healthcare professionals across our system will have received the [National Patient Safety Alert](#) (NatPSA/2023/013/MHRA) regarding organisations to prepare for new regulatory measures for oversight of prescribing valproate to new patients and existing female patients. The new regulations for oral sodium valproate, valproic acid and valproate semi sodium (valproate) from January 2024 state the following.

1. Valproate must not be started in new patients (male or female) younger than 55 years, unless two specialists independently consider and document that there is no other effective or tolerated treatment, or there are compelling reasons that the reproductive risks do not apply.
2. At their next annual specialist review, females of childbearing potential and girls should be reviewed using a revised valproate Risk Acknowledgement Form, which will include the need for a second specialist signature if the patient is to continue with valproate and subsequent annual reviews with one specialist unless the patient's situation changes.

Further information from the Medicines and Healthcare products Regulatory Agency (MHRA), on the risks of valproate and advice on management of risks is [available here](#).

We know that many organisations across Frimley have done considerable work throughout the years to ensure the safety of women and people of childbearing potential taking valproate– and are very appreciative of your support for this.

In response to the National Patient Safety Alert, a **Frimley ICS valproate safety implementation Group** has been set up to co-ordinate the implementation of the new regulatory measures, with representation from the relevant specialities outlined in the alert. The Group are working towards updating all local guidance and protocols, striving to understand the needs of the affected population and the patient experience, including those people most at risk of health inequalities and identifying and planning the clinical resource required to implement the new safety measures.

The Group will meet monthly and has had four meetings to date. Thank you to colleagues who have offered their time and expertise to this work, and we look forward to being able to engage more widely as the work progresses.

While we develop a practical and efficient process that works well for everyone, please continue to follow the [current safety measures for valproate](#) for any girls, women and people of childbearing potential and review your existing systems and processes to minimise any risk of harm including the use of the annual health checks where appropriate.

Updated safety and educational materials for both healthcare professionals, patients and their family/carers are available [here](#) and on DXS. Additional resources in plain English are also being developed locally. **Please ensure that existing patients and family/carers are provided with the updated patient information.**

Any females and people of childbearing potential who are not currently under a specialist should be given the updated safety information and referred to the appropriate specialist.

We have been informed by the MHRA that further information regarding the paternal risk of valproate will be communicated by April. In the meantime, male patients considering starting a family can be referred to their specialist for advice and guidance.

Patients on valproate must be informed not to stop taking their treatment without advice from their specialist.