

September 2024

General Practice Actions for The Safe Use of Valproate in Men within NEL

Valproate (sodium valproate, valproic acid and valproate semisodium) is primarily used in epilepsy and bipolar disorder. It is also used outside of the license ('off label') to treat other conditions. Valproate is subject to a national patient safety alert due to significant risk of harm to babies upon exposure during pregnancy. New evidence has shown a possible association between valproate use in men at conception with increased risk of neurodevelopmental disorders in children.

MHRA UPDATES- NEW SAFETY MEASURES – VALPROATE USE IN MEN: AS A PRECAUTION, MEN AND THEIR PARTNERS SHOULD USE EFFECTIVE CONTRACEPTION

Due to new evidence of possible harms of valproate in men, the **MHRA has issued [new safety measures](#) to further support prescribers around the safe use of valproate in all men and their partners.**

To strengthen the governance relating to the safe use of Valproate, the North East London Teratogenic Medicines Safety Improvement group will provide oversight to support providers (primary and secondary care, mental health trusts) with the implementation of these new safety measures.

OptimiseRx messages have been updated to reflect this alert. Please review prescriptions and patients in line with the messages.

Action for General Practices:

- Initiate an EMIS (or SystemOne) search to identify male patients prescribed valproate.
- Inform male patients (of any age) who may father children while they are taking valproate or in the 3 months after stopping valproate, there is a potential small increased risk of the child being diagnosed with a mental or movement related developmental disorder (neurodevelopmental disorder) at initiation of valproate or at their next regular treatment review
- as a precaution, recommend that male patients use [effective contraception](#) (condoms, plus contraception used by the female sexual partner) throughout the valproate treatment period and for 3 months to pass after stopping valproate,
- recommend they allow 3 months to pass (e.g. one complete sperm cycle with no valproate exposure) before trying to father a child
- at the next regular treatment review, discuss with men on oral valproate treatment whether they are planning a family in the next year and if they are, refer to a specialist to discuss alternative treatment options
- advise male patients, **do not stop taking valproate** unless you are advised to do so by a healthcare professional
- if a female patient reports they are pregnant or planning a pregnancy with a man on valproate (including those undergoing IVF), refer for prenatal counselling
- advise men not to donate sperm during valproate treatment and for 3 months after stopping valproate
- Further information and advice will be added to the valproate patient guide; in the meantime see MHRA's [Advice for male patients on valproate to use contraception](#) and [visual risk communication diagram to be used by a healthcare professional when counselling on the risks](#).
- For further details about the MHRA Drug Safety Update visit [valproate use in men as a precaution: Men and their partners should use effective contraception](#)
- Please continue to report suspected adverse drug reactions to the [Yellow Card scheme](#).
- Please continue to report medicines safety incidents to [Learning From Patient Safety Events](#)