NHS
Cornwall and Isles of Scilly

Guidance for men prescribed valproate in general practice

In September 2024 the MHRA released a drug safety update regarding valproate (sodium valproate, valproic acid and valproate semisodium) use in men. Valproate is primarily used in epilepsy and bipolar disorder but is also used to treat other conditions outside of its licence (off-label).

This was in response to a retrospective observational study that indicated a possible association between valproate use in men around the time of conception and an increased risk of neurodevelopmental disorders in their children. As a result of this health care professionals were asked to inform male patients who may father children of this possible increased risk and the recommendation to use effective contraception (condoms plus contraception used by the female partner) during valproate treatment and for at least 3 months after stopping valproate.

This alert superseded the drug safety update in January 2024 which mentioned the risk of impaired fertility in males.

Detailed background information can be found in the MHRA's public assessment report.

Updated safety and educational materials are now available in the June 2025 drug safety update

Informing patients of the risk

Practices need to inform all male patients of the risks associated with their prescription of valproate. There is a professional responsibility and failure to inform patients of the risk may leave the prescriber open to a claim or complaint to the regulators. The information is expected to come from primary care so there is no need for referral into secondary care for this reason alone. Practices can decide on how to communicate this risk in any way that they feel meets the patient's needs. Electronic messages (for example AccuRx) could be considered appropriate for some, or all male patients prescribed valproate.

Any registered healthcare professional can undertake these consultations. For example, GPs, pharmacists and nurses who are confident and competent to complete the consultation.

Patients should be advised **not to stop taking valproate** unless advised to do so by a healthcare professional. If a patient wishes to discuss their treatment options, please refer them to their specialist.

- Mental health – through the single point of access.

- Neurology – through ERS. If already under regular follow up an email to the team or advice and guidance can be used.

Support materials

Please visit the MHRA website for the most up to date support materials (as of June 2025). Resources include a patient guide, risk acknowledgement form and healthcare professionals guide.

The GPhC have a dedicated page for sodium valproate resources and information.

CPPE offer training Valproate: the hard conversations - focal point : CPPE

Risk acknowledgement forms

Only new patients started on valproate after 31 January 2024 require a risk acknowledgement form (RAF). This will need to be completed by the initiating specialist. These forms do not need to be completed annually. In February 2025 the MHRA published a Drug Safety Update. This states that the requirement for a review by two specialists remains in place for patients initiating valproate under 55 years of age, but the Commission on Human Medicines have advised that it will not be required for men (or males) currently taking valproate.

The MHRA have produced three infographics to clarify in which situations review by two specialists may be required

For female patients under 55 years old

For male patients under 55 years old

For male and female patients 55 years and older

Age range

There is no upper age-limit on this alert.

Trans women

The MHRA publication refers to men and males. General practices are advised that the alert applies to anyone who can biologically father children. Practices should consider this when searching their systems for at-risk patients as trans women may not be included in their search results of male patients.

Version control

Version number	Revision date	Revision by	Nature of revisions
1.0	May 2025	Joanna Lawrence Stacie Tregonning	Initial version approved by CAPC
1.1	May 2025	Medicines optimisation team	Formatting and style

Version number	Revision date	Revision by	Nature of revisions
1.2	June 2025	Joanna Lawrence	Addition of support materials from June 2025 DSU.