

Valproate Resources

To support the implementation of these measures for valproate, the following safety and educational materials are available:

- <u>Patient guide for women</u>
- Patient guide for men
- These guides provide 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.
- <u>Healthcare Professional Guide</u>: Provides updated information for healthcare professionals on the risks of valproate in pregnancy and the risks for male patients, the new conditions for valproate prescribing and key points for patient discussions.
- <u>Annual Risk Acknowledgement Form</u>: For female patients starting valproate and at annual review. 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.
- <u>Risk Acknowledgement Form for male patients starting valproate</u>: Used to support and record the discussion between the patient and specialist prescriber of the risks associated with valproate in males when starting treatment with valproate and to record the decision of the countersigning specialist. This is only to be completed at initiation of valproate.
- <u>Patient card</u>: Provides key information for female patients receiving valproate on contraception and pregnancy prevention.
- <u>Pharmacy poster</u>: Provides important actions for pharmacists dispensing valproate to female patients.
- <u>Warning stickers</u>: To be added to packaging of medicine in exceptional circumstances where the original pack cannot be dispensed.
- <u>MHRA infographics</u> which have been produced 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
 - $\circ ~$ for male and female patients 55 years and older
- BNSSG Original Pack Dispensing of Valproate Exceptions Risk Assessment Form: <u>https://remedy.bnssg.icb.nhs.uk/formulary-adult/local-guidelines/4-central-nervous-</u> <u>system-guidelines/</u>

See <u>Product Information</u> for valproate medicines, including the Patient Information Leaflet.

Patient support networks

Patient support networks such as:

• <u>Bipolar UK</u> - 0333 323 3880

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- <u>Epilepsy Action</u> 0808 800 5050
- <u>Epilepsy Society</u> 01494 601 400
- <u>Mind</u> 0300 123 3393

If patients experience any side effects to valproate medicines, you can report these to MHRA using the <u>Yellow Card Scheme</u>.

If a patient or their child has been affected by valproate medicines, they can also contact a support network such as:

Organisation for Anti-Convulsant Syndrome - OACS - 07904 200364

Useful links:

- Association of British Neurologists: ABN Guidelines for Valproate prescribing in Adult (16 and over) Neurology (June 2025)- <u>2025-06-12-ABN Guidance Valproate update June25.pdf</u>
- Guidance: Valproate use by women and girls <u>https://www.gov.uk/guidance/valproate-use-by-women-and-girls</u>
- Research and analysis: Valproate: review of safety data and expert advice on management of risks - <u>https://www.gov.uk/government/publications/valproate-review-of-safety-data-andexpert-advice-on-management-of-risks</u>
- Royal College of Obstetricians & Gynaecologists 'Valproate Use in Women and Girls of Childbearing Years' - <u>https://www.rcog.org.uk/guidance/browse-all-guidance/other-guidelines-and-reports/valproate-use-in-women-and-girls-of-childbearing-years/</u>
- The Faculty of Sexual and Reproductive Healthcare 'FSRH CEU Statement: Contraceptive Choices and Sexual Health for Transgender and Non-Binary People (October 2017)' https://www.fsrh.org/Search?SearchTerms=transgender
- Bulletin, Resource: Community Pharmacy Patient Safety Group 'Valproate Safety' <u>https://pharmacysafety.org/2018/06/25/valproate-safety/</u>
- The General Pharmaceutical Council (GPHC) 'Sodium valproate resources and information' -<u>https://www.pharmacyregulation.org/standards/guidance/sodium-valproate-resources-and-information</u>
- Guidance: Full pack dispensing of valproate-containing medicines -<u>https://www.gov.uk/government/publications/full-pack-dispensing-of-valproate-containing-medicines</u>
- National Patient Safety Alert: Valproate: organisations to prepare for new regulatory measures for oversight of prescribing to new patients and existing female patients
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(NatPSA/2023/013/MHRA) - <u>https://www.gov.uk/drug-device-alerts/national-patient-safety-alert-valproate-organisations-to-prepare-for-new-regulatory-measures-for-oversight-of-prescribing-to-new-patients-and-existing-female-patients-natpsa-slash-2023-slash-013-slash-mhra</u>

- MHRA Drug Safety Update Jan 2024: <u>https://assets.publishing.service.gov.uk/media/65ae8f33fd784b0010e0c688/January_DSU_P_DF.pdf</u>
- MHRA Drug Safety Update 2025: <u>https://www.gov.uk/drug-safety-update/valproate-belvo-convulex-depakote-dyzantil-epilim-epilim-chrono-or-chronosphere-episenta-epival-and-syonellv-review-by-two-specialists-is-required-for-initiating-valproate-but-not-for-male-patients-already-taking-valproate
 </u>
- FSRH CEU Statement: Contraception for women using known teratogenic drugs or drugs with potential teratogenic effects (February 2018): <u>https://www.fsrh.org/Public/Documents/fsrhceu-statement-contraception-for-women-using-known-teratogenicdrugs.aspx?WebsiteKey=f858b086-d221-4a83-9688-824162920b1b
 </u>
- MHRA Drug Safety Update June 2025: <u>Valproate (Belvo, Convulex, Depakote, Dyzantil, Epilim, Epilim Chrono or Chronosphere, Episenta, Epival, and Syonell ▼): updated safety and educational materials to support patient discussion on reproductive risks</u>