

## VALPROATE- ADVICE FOR ALL HEALTHCARE PROFESSIONALS WHEN DISCUSSING NEW RECOMMENDATIONS FOR EXISTING MALE PATIENTS



<b>TARGET AUDIENCE</b>	Medical, nursing and pharmacy staff working within primary and secondary care in NHS Lanarkshire
<b>PATIENT GROUP</b>	Male patients of any age prescribed valproate

### Clinical Guidelines Summary

- Updated guidance from the MHRA has advised of possible association between valproate use by men around the time of conception and increased risk of neurodevelopmental disorders in their children.
- The MHRA has recommended that healthcare professionals (HCP) should advise patients of this risk when valproate is started or at the next review of treatment.
- It is recommended that these discussions are best managed by the specialist service prescribing or recommending the prescribing of valproate (neurology or mental health).
- The role of the non-specialist HCP is to support the facilitation of the review by the specialist team.

## **Valproate: new recommendations**

- In September 2024, the MHRA issued an updated alert on a possible association between valproate use by males around the time of conception and increased risk of neurodevelopmental disorders in their children, as well as further clarification regarding the process in February 2025;

<https://www.gov.uk/drug-safety-update/valproate-use-in-men-as-a-precaution-men-and-their-partners-should-use-effective-contraception> - GOV.UK ([www.gov.uk](http://www.gov.uk)).

<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>

- Included in this alert are specific recommendations for health care professionals (HCPs) in advising patients who may father children of the possible risk when valproate is started or at their next regular treatment review. This change is in addition to the safety measures introduced in January 2024 advising that two specialists must support the use of valproate in new male patient and new/ existing female patients.

<https://www.gov.uk/drug-safety-update/valproate-belvo-convulex-depakote-dyzantil-epilim-epilim-chrono-or-chronosphere-episenta-epival-and-syonellv-new-safety-and-educational-materials-to-support-regulatory-measures-in-men-and-women-under-55-years-of-age>

- The MHRA have not yet differentiated between recommended actions for various HCPs as they have done with previous valproate alerts.

Discussions of this nature that may have an impact on the patient's ongoing engagement with treatment are best managed by the **specialist service** prescribing or recommending the prescribing of valproate (neurology or mental health).

There are significant risks associated with stopping valproate (for both neurological and mental health conditions) and decisions that may impact on ongoing treatment should be made **collaboratively between the patient and the specialist service**.

**No patient should stop taking valproate without talking to the HCP who is managing their care.**

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### Advice for specialist HCPs

- Communicating risk is a challenge; risks are difficult for HCPs to quantify so are likely to be especially difficult for patients to quantify risks and make informed choices about treatment.
- Shared decision making is about empowering and supporting staff and patients in a collaborative approach that enables decisions on benefits, risks, choices and on what matters most for the individual to be made.
- Consider the '5 questions' framework to support and guide the consultation and decision;

#### **Need; Benefit; Risks; Choice; Doing nothing**



- When approaching this conversation;
  - Manage the conversation sensitively. This is potentially a very emotive discussion.
  - Consider the language/terminology used to describe these risks
  - Consider what you know about the patient's personal history.
    - Do they already have children who were conceived when prescribed valproate and are potentially concerned about historical risks?
    - Are the patient and partner planning a pregnancy?
  - There are potentially significant risks to patients' ongoing engagement with treatment if these discussions are not managed well.

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### Advice for non-specialist HCPs

- The main role of the non-specialist HCP should be to support facilitation of the review by the specialist team.
- In the event that patients ask for advice about this alert;
  - Consider the full clinical picture; what you know about the patient; other medication they are prescribed and potential indication for valproate (neurological or mental health.)
  - Would the discussions around new valproate advice be more appropriately managed by a HCP that knows patient and/or the clinical background to valproate better e.g. a specialist prescriber (neurologist or psychiatrist)?
  - Follow the principles within 'Advice for specialist HCPs.'
  - If in doubt, contact the patient's specialist team to discuss.

### **Signposting**

- Advice materials from the MHRA are due to be updated.
- In the meantime, patient information and infographics outlining the new advice is included in the MHRA alerts;  
[Valproate use in men: as a precaution, men and their partners should use effective contraception - GOV.UK \(www.gov.uk\)](#)  
[Valproate \(Belvo, Convulex, Depakote, Dyzantil, Epilim, Epilim Chrono or Chronosphere, Episenta, Epival, and Syonell ▼\): review by two specialists is required for initiating valproate but not for male patients already taking valproate- GOV.UK \(www.gov.uk\)](#)
- Choice and Medication® patient info leaflets are another source of reliable patient information on medications used within mental health settings. Their leaflets are designed to help service users, carers and family members understand their medicines better, and to make more informed decisions, best as part of a discussion with a healthcare professional <https://www.choiceandmedication.org/nhs24/>

### **References**

1. Drug Safety Update volume 18, issue 2: September 2024: 1. [www.gov.uk](http://www.gov.uk)
2. MHRA Safety Update volume 18, issue 7: February 2025: 1 [www.gov.uk](http://www.gov.uk)

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## Appendices

### 1. Governance information for Guidance document

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CHANGE RECORD			
Date	Lead Author	Change	Version
Dec 24	L Templeton	<i>New guidance</i>	1

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