
Update from the Valproate Safety and Implementation Group

This update is for healthcare professionals in Cambridgeshire and Peterborough

Situation

- The local Valproate Safety and Implementation Group (VSIG) in Cambridgeshire and Peterborough are working towards developing a pathway across all clinical services involved with shared responsibilities for the safe prescribing of valproate, which will define the roles of each service within the shared pathway.
- An action and improvement plan has been developed in line with the actions within the [National Patient Safety Alert](#) (issued 28 November 2023) with system wide implementation measures planned to embed practices locally to support safe prescribing of valproate in children and adults (women and men) under 55 years.
- As you are aware, new regulatory measures have been introduced to reduce the harms from valproate, including the significant risk of serious harm to the baby if taken during pregnancy and the risk of potential impaired fertility in males.
- **Full implementation of the new regulations is not yet in place locally and the VSIG request that the existing valproate prescribing practices should continue.**
- All healthcare professionals should consult the [Patient Information Leaflet](#) and new [Patient Guide](#) for information about the risks of valproate. There is also a [Healthcare Professional Guide](#) for your review available. Please find the updated [Annual Risk Acknowledgement Forms \(ARAF\)](#) for your review.
- All healthcare professionals should report suspected adverse drug reactions associated with valproate including valproate exposed pregnancies (planned and unplanned) via the [Yellow Card](#) system.

Actions for General Practice and Community Pharmacists:

- Identify patients using valproate and continue to prescribe and dispense valproate including for patients where there is not an up-to-date ARAF. Valproate should be [dispensed](#) in the manufacturer's original full pack.
- Remind patients on valproate to not stop taking their treatment without advice from their specialist.
- Ensure girls and women of childbearing potential on valproate have appropriate pregnancy prevention measures in place (or are not at risk of pregnancy and excluded from pregnancy prevention measures) and expedite access to contraception for women and girls for whom this is not already in place, and who may need to start valproate.
- Remind patients to attend any offered appointments to discuss their treatment plan and to talk to a healthcare professional if they have any concerns.

- Urgently refer women on valproate who are planning to conceive to the specialist who initiated valproate treatment. Provide the women with the [Patient Guide](#) and advise such women to continue to use effective contraceptive measures until reviewed by their specialist.
- As a precaution, advise any male patients under 55 years on valproate who are planning a family within the next year to discuss treatment options with a healthcare professional. See [Drug Safety Update \(22 January 2024\)](#) for further information.

Actions for Specialists in Paediatrics/Paediatric Neurology/Adult Neurology/Epilepsy (including Specialist Nurses) /Psychiatry including Learning Disability:

- Only introduce valproate after other medications of lower reproductive risks have failed (unless in exceptional circumstances such as status epilepticus and particular paediatric epilepsy syndromes) and follow local arrangements for management of such patients i.e. adult patients with epilepsy who have continuing seizures despite two antiseizure medications at therapeutic doses should be referred to your local specialist epilepsy clinic.
- Ensure those commencing valproate:
 - Have been counselled about the reproductive risks of valproate.
 - Have been provided with the [Patient Guide](#).
 - Comply with the pregnancy prevention programme (or are not at risk of falling pregnant or conceiving).
 - Have an ARAF completed by the primary specialist.
- Discuss with colleagues how to implement the second counter signatory requirements including use of existing, or creation of new, specialist multi-disciplinary teams (MDTs).
- Alert through your usual organisational governance structures and via the Integrated Care Board Medicines Optimisation Team (cpicb.prescribingpartnership@nhs.net) of any difficulties with implementation of the new regulatory measures so possible mitigation or support can be considered by the local VSIG.
- Prioritise for review women on valproate who wish to conceive, or those taking valproate who are not on highly effective contraception, who have not already been counselled about the reproductive risks by a specialist in their condition.