

Medicines

Optimisation **intervention brief**

Title of Intervention:
Sodium valproate safety
WHAT?
<ul style="list-style-type: none"> • Ensure valproate medicines are no longer used in women or girls of childbearing potential unless a Pregnancy Prevention Programme is in place. The latter will ensure all women and girls (and their parent, caregiver, or responsible person, if necessary) are fully informed of the risks and the need to avoid exposure to valproate medicines in pregnancy. • Ensure valproate medicines are not used in girls and women of childbearing potential unless there is no suitable alternative, as judged by a specialist experienced in the management of epilepsy or bipolar disorder.
WHY?
<ul style="list-style-type: none"> • Valproate is highly teratogenic and evidence supports that use in pregnancy leads to physical birth defects in 10 in every 100 babies (compared with a background rate of 2 to 3 in 100) and neurodevelopmental disorders in approximately 30 to 40 in every 100 children born to mothers taking valproate. • Previous communications about the risk of neurodevelopmental disorders and the recommendation that women and girls of childbearing potential use effective contraception had little impact on prescribing. • Data from the Clinical Practice and Research Datalink show that pregnancies continue to be exposed to valproate medicines. Additionally, patients have reported that they still are not receiving the necessary information to make an informed decision in many cases. • Data from the NHS BSA suggests there are approximately 156 women of childbearing age are currently prescribed valproate within West Hampshire.
WHO?
<ul style="list-style-type: none"> • All females of childbearing potential prescribed valproate medicines or being considered for treatment with valproate medicines.
TIPS?
<ul style="list-style-type: none"> • Valproate medicines are indicated for the treatment of epilepsy and bipolar disorder. Epilim▼ and Depakote▼ are the most commonly dispensed valproate medicines in the UK. Other brands available are Convulex▼, Episenta▼, Epival▼, Kentlim▼, Orlept▼, Syonell▼, and Valpal▼.
HOW?
<ul style="list-style-type: none"> • Whilst the responsibility for implementing the required actions rests with the GP surgery, the CCG medicines optimisation team has an important role in supporting that implementation. • The following action plan is to ensure that the MOT support is provided to all practices in West Hampshire and at the end of the process, practices and the CCG are assured that the required actions have been taken. <p>ACTION PLAN</p> <ol style="list-style-type: none"> 1. Confirm that the practice are aware of where to locate resources for the following information packs. (Links can be found in the further information section of this document). 2. Import standard search for all potential at risk patients on GP clinical system (EMIS Web/SystemOne). 3. In agreement with the practice, identify all potential at risk patients.

4. Agree with the practice how at risk patients should be contacted and recalled to:
 - Provide the Patient Guide,
 - Check that a specialist has reviewed them in the last year
 - Check that they are on highly effective contraception.
5. Support the implementation of Action 4 and agree a target date for this to be completed.
6. In agreement with the practice, undertake an audit to ensure that **all at risk patients** have the following recorded in their clinical record
 - At least one highly effective contraceptive, preferably a user independent form such as an IUD or an implant OR two complementary forms of contraception including a barrier method.
 - Specialist review in the last year
 - On the PREVENT programme
 - Signed annual risk acknowledgement form
 - Up-to-date annual risk acknowledgement form signed before a repeat prescription is issued
7. MOT member collating the audit information should forward this on to the designated CCG pharmacy technicians responsible for locality data collection.
8. PLEASE NOTE: Valproate Pregnancy Prevention Programme: temporary advice for management during coronavirus (COVID-19) [Valproate Pregnancy Prevention Programme: temporary advice for management during coronavirus \(COVID-19\) - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/consultations/valproate-pregnancy-prevention-programme-temporary-advice-for-management-during-coronavirus-covid-19)

SO WHAT?

- A reduction in avoidable harm/ teratogenicity to children of mothers exposed to valproate medicines during pregnancy

FURTHER INFORMATION

- [Drug Safety Update](#).
- [Patient card](#)
- [Patient booklet](#)
- [Booklet for healthcare professionals](#)
- [Valproate annual risk acknowledgement form](#)