

Valproate update: Pregnancy Prevention Programme

Sept 2018



Children born to women who take Valproate (Epilim[®], Depakote[®] and generic brands) during pregnancy are at significant risk of birth defects and neurodevelopmental disorders. Following a review of the data available, new regulatory measures have been implemented to avoid Valproate exposure in pregnancy: ***Valproate medicines must not be used in women and girls of childbearing potential unless the conditions of the Pregnancy Prevention Programme (PPP) are met AND only if other treatments are ineffective or not tolerated, as judged by an experienced specialist. Specialists must review patients at least annually, re-evaluate treatment as necessary and complete and sign the Risk Acknowledgement Form.***

The use of valproate in pregnancy is contraindicated for bipolar disorder and must only be considered for epilepsy if there is no suitable alternative treatment. **The following guidance has been issued for general practitioners:**

- Ensure continuous use of highly effective* contraception in all women of childbearing potential. Consider the need for pregnancy testing if not a highly effective method.
- Even if a female has amenorrhea she must still follow all the advice on highly effective contraception
- A patient guide must be provided to ALL patients [Valproate Patient Booklet DR18.pdf](#)
- All females between the ages of 8 and 55 years should be referred back to the relevant specialist for review of appropriateness of ongoing valproate treatment.
- Check that all patients have an up to date, signed, Annual Acknowledgement of Risk form each time a repeat prescription is issued
- Ensure the patient is referred back to the specialist for review annually
- Refer back to the specialist urgently (within days) in case of unplanned pregnancy or where a patient wants to plan a pregnancy.

All females between the ages of 8 and 55 years should be referred back to the relevant specialist for review of their valproate treatment. The referral form for Mental Health (LCFT) & Adult Neurology (LTHT) patients is available from: <http://www.elmmb.nhs.uk/elmmb-information/mhra-drug-safety-updates/valproate> NHS numbers for any paediatric patients should be sent to ELHT Pharmacy. If you would like support or more details please contact Medicines Management.

*Highly effective contraception is considered, for regulatory purposes, to be a user independent method such as long acting reversible contraceptive (LARC), copper intrauterine device (Cu-IUD), levonorgestrel intrauterine system (LNG-IUS) progestogen only implant (IMP) or female sterilisation. At least one highly effective method of contraception or two complementary forms of contraception (including a barrier method) should be used. Individual circumstances should be evaluated in each case.

For further information please contact the Medicines Management Team on 01282 644807 (EL CCG)