

## VALPROATE: safe prescribing and dispensing to women and girls

**The Pan Mersey Area Prescribing Committee recommends that valproate is initiated and supervised by an experienced specialist and only when other treatments are ineffective or not tolerated.**

### SAFETY

If valproate is taken during pregnancy, up to 4 in 10 babies are at risk of developmental disorders, and approximately 1 in 10 are at risk of birth defects [1]. Women of childbearing potential and girls (of any age) who are taking any medicine containing valproate, regardless of the indication, should have an annual risk assessment form (ARAF) completed by their specialist.

If the specialist considers that there are compelling reasons to indicate that there is no risk of pregnancy [1] then the patient does not need to be enrolled on the valproate pregnancy prevention programme (**prevent**). The reasons why a patient does not need to be enrolled on **prevent** should be documented on the ARAF. If the absence of risk of pregnancy is not permanent, the date for the next annual review must also be documented. The ARAF should be countersigned by the patient, carer, or responsible person [1].

#### General practitioners [1]

Check that all patients have an ARAF each time a repeat prescription is issued. Any decision to prescribe without the ARAF should be based on an assessment of the patient's needs. Refer patients back to their specialist for annual review unless the latest ARAF describes the absence of risk of pregnancy as permanent.

#### For patients enrolled on **prevent**

Check for the continuous use of highly effective contraception:

- one highly effective method of contraception, preferably a user independent form such as an intrauterine device or implant **or**
- two complementary forms of contraception including a barrier method.

Consider the need for pregnancy testing based on the failure rate of the type(s) of contraception used and the information provided by the patient. If there is a risk of pregnancy a urine pregnancy test should be completed. It may not be necessary to complete a pregnancy test at each follow up appointment.

Tell her to contact you immediately if she suspects there has been a problem with her contraception or she may be pregnant. Refer a patient with unplanned pregnancy to her specialist and ask for her to be seen urgently (within days). Inform her not to stop valproate.

Refer a patient planning to become pregnant to her specialist. Inform her not to stop contraception or valproate until told to by her specialist.

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### Off-label use

In circumstances where the conditions of **prevent** cannot be met it may be in the patient's best interest for prescribing to continue. Such off-label use requires the prescriber to, "take responsibility for prescribing the medicine and for overseeing the patient's care, including monitoring and follow up" [3]. Specialists must support generalists and meet as fully as possible the conditions of **prevent** following best practice for communication and record keeping. If it is necessary to continue valproate therapy, the rationale should be clearly documented.

### Specialists

#### *When considering treatment*

- Only start treatment with valproate if other treatments are ineffective or not tolerated.

#### *Before prescribing*

- Discuss the need for her to be on the **prevent** programme.
- Provide a Patient Guide and discuss the risks with the patient or carer, or both.
- Exclude pregnancy in women of childbearing potential by performing a serum pregnancy test.
- Arrange for highly effective contraception for women of childbearing potential.

#### *If it is necessary to treat or continue to treat*

- Complete the Annual Risk Acknowledgment Form with patient or carer, or both; give them a copy and send a copy to the GP.
- Make every effort to switch female children to alternative treatment before they reach adulthood [3].
- See the patient urgently (within days) if referred back for unplanned pregnancy or if she wants to plan a pregnancy.

### Pharmacists [1]

Provide a Patient Card every time valproate is dispensed and ensure the patient has a copy of the current Patient Guide. If the patient confirms that they already have a card, clearly document in the clinical record that no card was supplied. Offer a patient guide if the patient does not have one. Dispense valproate in the original package. If repackaging cannot be avoided always provide a copy of the patient information leaflet and add a sticker with the warning to the outer box.

If a woman of childbearing potential is not aware of the risks in pregnancy, the need for highly effective contraception, and the need for annual specialist review, dispense their medication and refer her to her GP (contact her GP directly if necessary).

### Gynaecologists and obstetricians, midwives, and nurses [1]

Provide information and counselling about the risks of using valproate during pregnancy, contraception methods, and pregnancy planning. When a patient consults for pregnancy refer her and her partner to her prescriber and to a specialist experienced in prenatal medicine for evaluation and counselling regarding the exposed pregnancy.

### Emergency physicians [1]

Ensure that any woman of childbearing potential using valproate is referred to her specialist for assessment. If she is pregnant, ensure that she is referred for urgent review (within days).

### Resources

*Medicines and Healthcare Products Regulatory Agency*

[Valproate use by women and girls](#)

[Patient card](#)   [Patient booklet](#)

[Booklet for healthcare professionals](#)

[Valproate annual risk acknowledgement form](#)

*Royal College of Obstetricians and Gynaecologists*

[Valproate Use In Women and Girls Of Childbearing](#)

[Years](#)

Supporting information

*Medicines for Children*

[Sodium valproate for preventing seizures](#)

[Sodium valproate and pregnancy - information for parents and carers](#)

[Sodium valproate and pregnancy - information for girls and young women.](#)

## References

- [1] Medicines and Healthcare products Regulatory Agency, "Valproate use by women and girls," 11 February 2021. [Online]. Available: <https://www.gov.uk/guidance/valproate-use-by-women-and-girls>. [Accessed 14 May 2021].
- [2] Medicines and Healthcare products Regulatory Agency, "Off-label or unlicensed use of medicines: prescribers' responsibilities," 11 December 2014. [Online]. Available: <https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities>. [Accessed 14 May 2021].
- [3] emc, "Epilim 200 mg Gastro-resistant tablets," Datapharm, 4 January 2021. [Online]. Available: <https://www.medicines.org.uk/emc/product/519>. [Accessed 14 May 2021].
- [4] Royal College of Paediatrics and Child Health, "Pre-procedure pregnancy checking for under-16s: guidance for clinicians," [Online]. Available: <https://www.rcpch.ac.uk/resources/pre-procedure-pregnancy-checking-under-16s-guidance-clinicians>. [Accessed 14 May 2021].
- [5] General Medical Council, "Good practice in prescribing and managing medicines and devices," 5 April 2021. [Online]. Available: <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices>. [Accessed 14 May 2021].