

Valproate ▼ : Pregnancy Prevention Programme

Valproate medicines are indicated for the treatment of epilepsy and bipolar disorder. In some cases valproate medicines are also used in “off label” indications, such as migraine.

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 (refer to the [BNF online](#) for product list).

REMINDER

Valproate is now contraindicated in girls and women of child bearing age unless they meet the conditions of the Valproate Pregnancy Prevention Programme ([prevent](#)).

- Valproate medicines should not be used in girls and women of child bearing potential unless other treatments are ineffective or not tolerated as judged by an experienced specialist¹.
- Children exposed to valproate in utero are at high risk of early neurodevelopmental disorders (in 30-40% of cases), including autism spectrum disorders, and congenital malformations (in approximately 10% of cases)².
- Healthcare professionals must familiarise themselves with the guidance and information resources available [here](#) from the Medicines and Healthcare products Regulatory Agency (MHRA).
- Both patient and clinician must sign the Valproate **Annual Risk Acknowledgement Form** when their treatment is reviewed annually by a specialist to confirm counselling has been given.

IMPORTANT ACTIONS FOR GENERAL PRACTICE – refer also to the [MHRA guidance](#) for detailed actions.

Identify **all females (aged 0 - 60)** of child bearing potential on valproate medicines. All patients will require a review. Patients can be prioritised for review as follows:

1. Women of child bearing age, not post-menopausal, who have not been reviewed by specialist within last 12 months. **Refer these patients to their Specialist.**
2. If of child bearing potential, check they are on highly effective contraception, if not then start one – see [toolkit](#) for details
3. Inform them of the known risks and ensure they understand that they must not get pregnant whilst taking valproate
4. Provide the [Patient Guide](#) (see information and support below)
5. Re-audit in 12 months to identify new patients on valproate

[Information and Support](#)

Copies of materials can be downloaded from <https://www.medicines.org.uk/emc>
Enter ‘valproate’ in search box and then click on ‘Risk Materials’ next to any of the medicines that appear.

▼ These medicines are subjected to additional monitoring.

Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

[References](#)

1. MHRA Drug Safety Update, April 2018: Valproate contraindicated in women and girls of childbearing potential unless conditions of Pregnancy Prevention Programme are met, available [here](#). Accessed 02.08.18
2. MHRA Drug Safety Update, January 2015: Medicines related to valproate: risk of abnormal pregnancy outcomes, available [here](#). Accessed 02.08.18

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South East London Area Prescribing Committee. A partnership between NHS organisations in South East London: Bexley/ Bromley/ Greenwich/ Lambeth/ Lewisham & Southwark Clinical Commissioning Groups (CCGs) & GSTFT/KCH/SLAM/Oxleas NHS Foundation Trusts & Lewisham & Greenwich NHS Trust