

## Responsibilities when supporting females of childbearing potential taking sodium valproate and valproic acid (valproate)

**Valproate medicines must not be used in female patients of childbearing potential unless the Pregnancy Prevention Programme is in place <sup>(1,2,3)</sup>**

### Responsibilities of all Healthcare Professionals:

1. The requirement for a Pregnancy Prevention Programme (PPP) is applicable to all premenopausal female patients unless the prescriber considers that there are compelling reasons to indicate that there is no risk of pregnancy
2. As for any medicine use that does not comply with the conditions of the licence would be off-label and carry the accompanying responsibilities
3. There will be some instances where patients may refuse an investigation or treatment. Under those circumstances you must respect a patient's decision. The Royal College of General Practitioners Guidelines have clear recommendations for what to do in those circumstances, in which case the guidance should be followed, and all steps clearly recorded<sup>(3)</sup>.

### Actions for Specialists in the management of epilepsy or bipolar disorder:

1. Recall or book review appointments at least annually with female patients of childbearing potential under the Pregnancy Prevention Programme
2. Re-evaluate treatment as necessary – valproate should only be used in female patients of childbearing potential when other treatments are ineffective or not tolerated
3. Clearly explain the conditions as outlined in the PPP supporting materials <sup>(2)</sup>
4. Complete and sign the valproate Annual Risk Acknowledgement Form
5. Provide copies of the Annual Risk Acknowledgement Form to the patient, carer or responsible person AND send a copy to the GP
6. Support patients urgently if a pregnancy occurs or planning a pregnancy whilst on valproate

### Actions for General Practice:

1. Identify and keep a practice valproate register of all female patients of childbearing potential prescribed valproate
2. Review each patient on a monthly basis recording actions on the register
  - Check there has been a review by a specialist in the last year and that an in-date Annual Risk Acknowledgement Form has been received by the practice
  - Ensure highly effective contraception\* is being used. If the specialist considers there is no risk of pregnancy (for example, pre-menarche or post-menopausal) the reasons for not enrolling on the PPP must be recorded on the Annual Risk Acknowledgement Form
3. Ensure the patient has the patient information materials every time the patient attends their appointments or receive their prescriptions
4. Support women to seek advice from specialists (original prescriber and obstetrician) as soon as possible if a pregnancy occurs or planning a pregnancy

### **Actions for Dispensing Pharmacists:**

1. Discuss risks in pregnancy with all female patients of childbearing potential when valproate medicines are handed out
2. Dispense whole, original packs whenever possible with the patient information leaflet
3. Ensure the medicines dispensed have a warning label
4. Check patients have the valproate patient guide and have seen their GP or specialist to discuss their treatment and the need for contraception
5. Support patients to seek advice from specialists (original prescriber and obstetrician) as soon as possible if a pregnancy occurs or planning a pregnancy

### **Actions for Providers of Adult Social Care and their Staff:**

1. Identify female patients of childbearing potential who are taking valproate - you should not assume that a patient with a learning disability is not sexually active
2. Support patients to attend their GP and / or specialist appointments for review
3. Work with healthcare professionals to provide information about the Pregnancy Prevention Programme - this should be in an accessible format where necessary, for example easy read (for example: <https://www.fpa.org.uk/product/contraception-a-guide-for-people-with-learning-disabilities>)
4. Hold a copy of the Annual Risk Acknowledgement Form if the patient is unable to do so themselves
5. Proactively support female patients with their contraceptive needs, where necessary
6. If a pregnancy occurs, providers must support patients to seek advice from specialists (original prescriber and obstetrician) as soon as possible

A video is available to support healthcare professionals in understanding their responsibilities and implementing the 2018 regulatory measures, including the Pregnancy Prevention Programme and regular patient reviews. <https://youtu.be/VuBq2M1Me04>

### **\*Contraception**

At least one highly effective method of contraception or two complementary forms of contraception including a barrier method should be used.

Examples of highly effective contraception include:

- copper intrauterine device
- levonorgestrel intrauterine system
- progestogen-only contraceptive implant

User dependent methods include the condom, cap, diaphragm, oral contraceptive pill (COC) and fertility awareness-based methods. These must be used together with a barrier method of contraception. Frequent pregnancy testing should be carried out.

### **References:**

1. <https://www.cqc.org.uk/guidance-providers/adult-social-care/high-risk-medicines-valproate>
2. <https://www.gov.uk/drug-safety-update/valproate-pregnancy-prevention-programme-actions-required-now-from-gps-specialists-and-dispensers>
3. [Pan College Guidance Document on Valproate Use V2.1.pdf \(rcpch.ac.uk\)](#)