



## **Valproate Pregnancy Prevention Programme: temporary advice for management during coronavirus (COVID-19) pandemic**

Guidance for initiation of valproate in female patients and for annual review and pregnancy testing to support adherence to pregnancy prevention requirements during the coronavirus pandemic.

### **Temporary guidance for specialists**

Valproate is harmful if used in pregnancy. Children exposed to valproate in utero have a very high risk for congenital malformations (10% risk) and neurodevelopmental disorders (30–40% risk). Valproate medicines (for any indication) are therefore contraindicated in girls and women of childbearing potential unless the conditions of the [Pregnancy Prevention Programme \(PPP\)](#) are fulfilled.

During the current coronavirus (COVID-19) pandemic, to support adherence to the pregnancy prevention requirements for girls (of any age) and women of childbearing potential taking valproate, we are aware that changes to the usual operating of the PPP may be required, particularly for patients who are shielding due to other health conditions.

The MHRA has sought advice from expert advisors, including healthcare professionals managing patients on valproate and patient representatives affected by the harms of valproate in pregnancy. We issue the following temporary advice to ensure the PPP requirements can be met safely. We will communicate again once these temporary recommendations are no longer considered necessary.

### **Initiation of valproate**

Initiation of valproate in girls (of any age) and women of childbearing potential requires face-to-face consultation (with appropriate social distancing) except where the patients are shielding due to other health conditions. Where a patient is shielding, a remote consultation should be considered, based on an individual risk assessment carried out by the clinician in charge. The risk assessment should be documented in the notes.

### **Annual review of existing patients**

The licence terms of valproate medicines state that patients on valproate who have experienced menarche must have a review at least annually with the prescribing specialist to reassess the need for valproate therapy and consider alternative treatment options. Annual reviews should not be delayed due to the pandemic. No woman or girl should stop taking valproate without first discussing it with their doctor.

Consideration should be given to the need for a “responsible person” to support the discussion. This is defined as a parent/legal guardian or person capable of giving consent on behalf of patients or acknowledging that the treatment is in the best interests of the patient, on behalf of minors or those without the capacity to make an informed decision

### **Arrangements for annual review**

For girls (of any age) and women of childbearing potential on valproate, specialist prescribers should undertake video virtual consultation (preferably) or telephone consultation (if video is not possible) with the patient in line with the following process:

1. Email or WhatsApp (if possible) the [Valproate Patient Guide](#), and the [Annual Risk Acknowledgment Form \(ARAF\)](#) when booking the virtual appointment. If the patients do not have access to emails/WhatsApp (or another method to receive electronic files), this should be

recorded in the notes and paper copies of the patient guide and ARAF sent to the patient by post.

2. Prior to the appointment, check that the patient has received the information.
3. At the appointment, go through the ARAF together and get verbal confirmation that the patient understands the requirements of the valproate PPP.
4. Ensure the patient has access to effective contraception. Where there are difficulties in accessing contraception, the [Faculty of Sexual and Reproductive Healthcare has issued guidelines](#); provision of contraception for patients on valproate is considered a priority service.
5. Document verbal confirmation that the patient understands the requirements of the PPP on the ARAF and record the reason a patient signature was not possible in the notes (remote working due to COVID-19).
6. Send a copy of the completed ARAF to the patient and their GP.
7. Ask the patient to confirm (via email/WhatsApp if possible) receipt of the ARAF, that it reflects the discussion with the prescriber and that they understand the requirements of the valproate PPP.
8. If (within 2 weeks) the patient refuses or fails to confirm in writing their receipt of the ARAF and their understanding of the requirements of the PPP, follow up with the patient to seek verbal assurance of receipt of the ARAF and understanding of the requirements and record this in the notes.

### **Pregnancy testing**

Where face-to-face consultation is not possible and pregnancy testing is required, home pregnancy testing could be acceptable, at the discretion of the clinician, provided the following minimum criteria are met:

1. Adequate instruction and support are provided. The pregnancy test should be sent to the patient by their clinic and this should include at least one spare test in case there needs to be confirmation of the result or one is damaged or misused. In exceptional circumstances, the healthcare professional should provide the patient with a list of acceptable test kits that the patient can procure, either directly from a pharmacy (by a relative or friend) or over the internet.
2. The pregnancy test meets the minimum required sensitivity (25 mIU/mL).
3. The result of the pregnancy test is verified by the prescriber. Ideally, the patient would take a photograph of the test and send this to the healthcare professional by email/video conferencing. If no email or video conferencing is available then a telephone description of the test result, make of kit, and how it was used would be a minimum requirement.

### **Call for reporting**

Valproate medicines are black triangle medicines and all suspected adverse drug reactions should be reported to the MHRA.

Healthcare professionals, patients, caregivers and are asked to submit all suspected side effect reports using the Yellow Card scheme electronically using:

- [the Yellow Card website](#)
- the Yellow Card app; download now from the [Apple App Store](#) or [Google Play Store](#)
- through some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank)