

Safe Valproate Prescribing in Female

Part A: Prescribing for New Starters

Specialist: Valproate must not be started in new patients younger than **55 years** unless

- **Two specialists** independently consider and document there is no other effective or tolerated treatment OR
- There are compelling reasons that the reproductive risks do not apply.

Specialist: Use a shared decision-making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling to enable the patient to reach an informed decision. Counselling should include the need for highly effective contraception. Decision Support Tools can be found here: [Is valproate the right epilepsy treatment for me?](#) Or [Decision support tool: bipolar disorder – is valproate the right treatment for me?](#)

No

Informed decision made to start valproate containing product.

Yes

Specialist: Document share decision outcome, re-evaluate treatment options as necessary.

Specialist: Obtain and document patient consent. Provide an appropriate patient information leaflet, a copy of the **Patient guide for female patients**

Specialist: Conduct required baseline investigations and initial monitoring of valproate as recommended by [SPS](#). Liaise with or refer to primary care or sexual health service to arrange for appropriate highly effective contraception as per FSRH guidance.

Specialist: Add patient to your valproate patient recall register if subsequent annual review is regulatory required.

Recall or book review appointments at least annually with females of childbearing potential under the Pregnancy Prevention Programme.

Specialist: Initiate and titrate treatment to the maintenance dose at ongoing scheduled review. Complete the shared care documentation and send to patient's GP practice detailing the diagnosis, current and ongoing dosage plan, any relevant test results and when the next monitoring is required.

Provide a copy of the risk assessment form(s) to primary care with relevant specialist team contact information for valproate query.

[Female Risk Acknowledgement Form](#) ; for female patients starting valproate and at annual review. For those where the potential for not becoming pregnant is permanent, only part 1 of the ARAF needs to be completed ONCE

General Practice:

At the point of accepting SCA and continued prescribing of valproate, **check there has been a completed risk assessment form documented with two specialist signatories for new initiations**

For **female patient(s)** If the specialist considers

- **Potential for not becoming pregnant is permanent**, the reasons for not enrolling on the Pregnancy Prevention Programme (PPP) must be documented in the primary care clinical system and read code PPP not needed (**Y2f18**). Hence annual recall of review ARAF is not applicable.
- **Female children who have not yet reached menarche**, patient(s) and their responsible person need to be made aware of the risk for the future. Remind to re-contact GP once female child using valproate reaches menarche. GP is responsible to facilitate patient to seek advice from specialist as soon as possible when the risk status has changed.
- **Women of childbearing potential (from menarche to menopause)** should be enrolled with PPP unless there are compelling reason that there is no risk of pregnancy as indicated by specialist. Where applicable, utilize Ardens "Valproate Monitoring Template" to document Pregnancy Prevention Programme (**Y20ab**) AND Valproate Annual Risk Acknowledgement form completed (**Y362e**) in the primary care clinical system. Prescribe or liaise with sexual health service to arrange appropriate *highly effective contraception* as per Faculty of Sexual Health and Reproductive Healthcare guidance.

Prescribe Valproate product as per shared care agreement, add patient to your surgery Valproate Register to facilitate local safe Valproate prescribing monitoring.

Part B: Day to Day Practice

General Practice
Continue to prescribe Valproate Containing Medicines via FP10.



	Secondary Care Activity (Specialist)
	Primary Care Activity (GP Practice)
	Community Pharmacy
	Maternity Service
	Sexual Health Service
	Adult Social Care

Community Pharmacy

- Unless there are exceptional circumstances, valproate -containing medicines must always be dispensed in the manufacturer's original full pack.
- Ensure patients have the valproate patient guide and have seen their GP or specialist to discuss their treatment and the need for highly effective contraception.
- If a woman of childbearing potential is not aware of the need for contraception and has not been seen by her GP/Specialist in the past year, dispense their medicine and refer them to their GP for a highly effective contraception discussion.
- Support women to seek advice from general practice or specialists as soon as possible if a pregnancy occurs or planning a pregnancy.



Patient receives supply of valproate product.



The CHM advised that the second specialist signatory could include the following:

- Consultant adult or paediatric neurologists • Consultant psychiatrists • Speciality and associate specialist doctors in psychiatry and neurology • Speciality doctors in psychiatry • Paediatrician with special interest in epilepsy • Paediatrician who regularly manages complex epilepsy or bipolar disorder • Epilepsy Nurse Consultant • Specialist Nurses in relevant disciplines

Specialist:

- Females of childbearing potential under the Pregnancy Prevention Programme will be recalled at least annually to assess the risk and benefit of ongoing usage of valproate containing medicines.
- Complete and sign the Female Valproate Annual Risk Acknowledgement Form. Including the process for providing copies of the ARAF to the patient, carer or responsible person AND communicating a copy of the ARAF with the patient's General Practice.

Adult Social Care:

- Identify women of childbearing potential who are taking valproate. It should not be assumed that a woman with a learning disability is not sexually active.
- Support women to attend their GP and/or specialist appointments for review.
- 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.
- Hold a copy of the annual risk acknowledgement form if the woman is unable to.
- Proactively support women with their contraceptive needs, where necessary. Be vigilant on any arising safeguarding issues.

Maternity services:

- Ensure effective protocol is in place to facilitate drug history taking and identify any pregnant person who may be prescribed valproate.
- If a pregnant person prescribed valproate is identified. Provide information about the risks of using valproate during pregnancy. Refer her and her partner to specialist who is experienced in prenatal medicine for evaluation and counselling regarding the exposed pregnancy.
- Support any pregnant person to seek advice from specialists as soon as possible if found to be prescribed valproate.
- Document and report any suspected adverse reactions or incident associated with valproate, including adverse pregnancy outcomes. Report as per organization medication safety event reporting protocol or via Learn from Patient Safety Events Service.

Sexual Health Services:

- Ensure effective protocol is in place to facilitate drug history taking and identify any female patient who may be prescribed valproate.
- Provide counselling on contraception methods and pregnancy planning.
- In the case where a highly effective contraception is not used. Patients need to be made aware of the teratogenic risks of valproate.
- Obtain informed consent from the patient to communicate with general practice about the contraception management plan.
- Support general practice on prescribing highly effective contraception, if clinically appropriate.

General Practice:

Develop a safe valproate prescribing and monitoring procedure which includes but is not limited to:

- Setting up and maintaining a surgery Valproate Register.
- Monthly/Quarterly running of valproate search* to identify any new patients prescribed valproate (either newly initiated or patients new to surgery).
- Documented the action taken to facilitate recalls and monitoring. Support patient to attend the specialist appointment for review.

For Female patient:

- Use of the designated valproate monitoring template in Ardens to ensure annual monitoring is accurately and clearly documented in the patient's record. To include but not limited to the following codes:
 - **Pregnancy Prevention Programme started (Y2f16)**
 - **Valproate Annual Risk Acknowledgement form completed (Y362e)**
 - **Referral for completion of Valproate Annual Risk Acknowledge Form (Y38a6)**
 - **Pregnancy Prevention Programme not needed (Y2f18)**
- At the point of continue prescribing valproate, 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 the patients has the patient information materials every time the patient attends their appointments or receive their prescriptions.
- Support women to seek advice from specialists as soon as possible if a pregnancy occurs or planning a pregnancy. Patient who are planning a family within next one to two years should speak to healthcare professional about their treatment.
- Prescribe or liaise with sexual health service to arrange appropriate *highly effective contraception* as per Faculty of Sexual Health and Reproductive Healthcare guidance.

Supporting Information

To support the implementation of the new measures for valproate, the following safety and educational materials are being made available:

- **Risk Acknowledgement Forms:**
 - **Female:** [Female Risk Acknowledgement Form](#) for female patients starting valproate and at annual review. Used to support and record the discussion between the patient and specialist prescriber on the risks associated with valproate in pregnancy and to record the decision of the countersigning specialist. At subsequent annual reviews only one specialist is required.
- [Healthcare professionals Guide](#): Provides updated information for healthcare professionals on the risks of valproate in pregnancy and the risks for male patients, the new conditions for valproate prescribing and key points for patient discussions.
- Patient guides for [female](#) and [male](#) patients: Provides those taking valproate (or their parent, caregiver, or responsible person) with updated information on the risks of valproate in pregnancy and the risks to male patients and what they need to do.
- [Patient Card](#): Provides key information for female patients receiving valproate on contraception and pregnancy prevention.
- [Pharmacy Poster](#): Provides important actions for pharmacists dispensing valproate to female patients.
- [Electronic Medicines Compendium](#). Links to the patient guide and patient card are also available via a QR code provided in the Patient Information Leaflets for Epilim and Depakote.
- **Highly effective contraception:**
 - [Guidance from Faculty of Sexual and Reproductive Health \(FSRH\)](#) Contraception for women using known teratogenic drugs or drugs with potential teratogenic effects.
FSRH advises highly effective contraception would include sterilisation and LARCs: copper IUDs, levonorgestrel IUSs, and progesterone-only implants (all have failure rate <1%; additional precautions not required). COCP and POPs have failure rate <9%, and progestogen-only injectables (DMPA) (although still a LARC) has failure rate of <6%; therefore, additional contraceptive precautions are advised for these contraceptives.
- Patient Support Networks: [Bipolar UK](#) - 0333 323 3880, [Epilepsy Action](#) - 0808 800 5050, [Epilepsy Society](#) - 01494 601 400, [Mind](#) - 0300 123 3393. For patients who have questions or concerns about the risks associated with valproate and pregnancy, please speak to your doctor, pharmacist or other healthcare professional.
- [Medicines & Healthcare products Regulatory Agency](#), Valproate: review of safety data and expert advice on management of risks.
- Information should be provided in an accessible format where necessary, for example easy read. Additional useful leaflets include:
 - Decision Support Tool: Is valproate the right epilepsy treatment for me? This tool is designed to help patient to understand the risk and benefits of valproate and support them to start or continue taking valproate containing medicines:
 - [Decision support tool: is valproate the right epilepsy treatment for me?](#)
 - [Decision support tool: bipolar disorder – is valproate the right treatment for me?](#)
 - [AWP patient information leaflets on valproate](#) which include very easy read leaflets and the leaflet in a range of languages. - Additional easy read leaflets and resources in range of languages.
 - [Valproate information - leaflets in 30 languages](#) - Southeast Regional Clinical Quality Improvement team have developed an information leaflet to support person-centred, informed discussions about how to take valproate as safely as possible. The leaflet has been translated into 30 languages
 - Where relevant, ensure the patient is aware of the obligation to inform the DVLA about a medical condition or disability or regular medication that affects driving <https://www.gov.uk/driving-medical-conditions>