BSW APC: BaNES, Swindon & Wiltshire (BSW) ICB, Avon & Wiltshire Mental Health Partnership NHS Trust (AWP), Royal United Hospitals Bath NHS Foundation Trust, Great Western Hospitals NHS Foundation Trust, Salisbury NHS Foundation Trust, HCRG Care Group, Swindon Community Health Services, Wiltshire Health & Care

SHARED CARE AGREEMENT

Sodium valproate and valproic acid (semi-sodium valproate) In this document, 'valproate' will be used to describe both drugs.

For women of childbearing potential. 'Childbearing potential' is used to describe a female child or any woman who can become pregnant even if the individual circumstances mean this is unlikely.

Amber TLS – 3 months

Valproate and male patients (*applicable to anyone who can biologically father children, including men or trans-women who retain the capability to generate sperm*). Valproate may cause infertility in men, with some toxic effects observed on the testes in animal studies, though it's unclear for humans. A meta-analysis found a slightly higher risk of neurodevelopmental disorders in children born to males taking valproate (4.0-5.6%) compared to those on other epilepsy drugs (2.3-3.2%), with an adjusted hazard ratio of 1.50. However, this risk is much lower than the 30-40% risk observed in children born to mothers taking valproate during pregnancy. For detailed information, refer to the PAR on Valproate Safety Data. The *Sep 2024 MHRA DSU Valproate Use in Men* provided new advice for managing male patients. **Whilst the focus of this BSW SCA is women of childbearing potential, a comprehensive local memo (inc. flowchart) advising BSW clinicians how to manage existing and new starters of valproate in male patients is published here. Also see Valproate Safety - Medicines**

Principles of Shared Care

Shared care agreements (SCAs) provide a framework for the seamless transfer of care from a hospital or specialist service setting to general practice, where this is appropriate and, in the patient's, best interest. When a specialist considers a patient's condition to be stable or predictable, they may seek the agreement of the GP (or other primary care prescriber) concerned and the patient to share their care.

Patients and/or carers must be centrally involved in any decision-making process. They should be supported by good quality information that helps them to both come to an informed decision about engagement in a shared care arrangement and sets out the practical arrangements for ongoing supplies of medicines.

The existence of a SCA does not necessarily mean that the GP has to agree to and accept clinical and legal responsibility for prescribing; they should only do so if they feel clinically confident in managing that condition. Clinical responsibility for prescribing is held by the person signing the prescription, who must also ensure adequate monitoring.

New regulatory measures for valproate, January 2024:

A. Valproate must not be started in new patients (male or female) younger than 55 years, unless two specialists independently consider and document that there is no other effective or tolerated treatment, or there are compelling reasons that the reproductive risks do not apply.

B. At their next annual specialist review, women of childbearing potential and girls should be reviewed using a revised valproate Risk Acknowledgement Form, which will include the need for a second specialist signature if the patient is to continue with valproate and subsequent annual reviews with one specialist unless the patient's situation changes.

Risk Acknowledgement Forms:

- Annual Risk Acknowledgement Form (ARAF): **Female patients** starting valproate and at annual review.
- Risk Acknowledgement Form (RAF) **Male patients** starting valproate.

These measures are **required** for people under the age of 55 because this is the age group most likely to be affected by the reproductive risks of valproate.

These risks should also be **considered** for men and women over the age of 55 years planning to have children.
Valproate is highly teratogenic (known risk of birth defects and neurodevelopmental disorders following use in pregnancy) and should only be prescribed for women of childbearing potential in exceptional circumstances and in line with the conditions in the existing **Pregnancy Prevention Programme (PPP)**.

Do not stop prescribing valproate unless recommended by the specialist team.

(The definition 'Specialist' in this SCA could include 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 or who regularly manages complex epilepsy or bipolar disorder; Epilepsy Nurse Consultant; Specialist Nurses in relevant disciplines. MHRA Valproate: review of safety data and expert advice on management of risks PAR Nov. 2023).

- Initiate treatment and prescribe for at least 3 months. This should be enough time to allow optimisation of treatment and demonstrate that the patient's response is consistent.
- Discuss the benefits, side effects and risks of treatment with the patient and provide a copy of the Patient Guide.
- Complete Annual Risk Acknowledgment Form (ARAF) with patient at initiation [*2 specialist signatories*] and annual review [*1 specialist signatory*]. Give patient a copy and send a copy to GP.
- Review concurrent medications for potential interactions prior to initiation.
- Undertake the clinical assessment and relevant monitoring at baseline and during the initiation period.
- Exclude pregnancy (by serum pregnancy test) and arrange for **highly effective contraception (see section 12)** before first prescription is issued.
- Communicate details of treatment to GP (in writing or via secure email) within the first month of treatment and ask the GP whether he or she is willing to participate in shared care.
- Discuss shared care arrangements with the patient/carer, obtain their consent and explain their responsibilities.
- Review the patient's condition and monitor response to treatment regularly where indicated.
- Inform the GP after each clinic attendance if there is any change to treatment or monitoring.
- Supply GP with clinic letter or discharge summary within 14 days of an outpatient review or inpatient admission, and inform GP if patient does not attend scheduled clinic appointments.
- Book in review appointments at least annually and continue to see the patient annually for review of the ARAF. Copies must be sent to the patient and their GP on an annual basis in a timely manner to enable valproate prescribing to continue in primary care.
- Ensure that clear arrangements exist for GPs to obtain advice and support.
- See the patient urgently without delay (within 2 working days) if referred back in case of unplanned pregnancy or within one month if she wants to plan a pregnancy.
- Report adverse events to the MHRA.
- Stop treatment where appropriate or provide GP with advice on when to stop.

Responsibilities of GP (The definition 'GP' in this SCA could include any suitably qualified Primary Care Prescriber)

- Reply to the request as soon as practicable if they are **unable** to support shared care (in writing or via secure email).
- Prescribe medicine at the dose recommended after the initiation period.
- Check the patient has an up to date, signed, ARAF filed in medical records each time a repeat prescription for valproate is issued. In the case of an absence of this, contact specialist.
- Undertake ongoing clinical assessment and relevant monitoring following initiation period.
- Ensure continuous use of **highly effective contraception (see section 12)** in all women of childbearing potential. Any contraceptive changes should be communicated promptly to the specialist.
- Consider the need for pregnancy testing if not on a highly effective method or any reason to suggest lack of compliance or effectiveness of contraception.
- Prescribe folic acid 5mg daily immediately, and refer back to specialist and maternity/obstetrics service urgently (same day) in case of unplanned pregnancy or where a patient wants to plan a pregnancy. Remind the patient not to stop taking valproate medicine in the interim.
- Review any new concurrent medications for potential interactions.
- Refer promptly to specialist when any loss of clinical efficacy is suspected (e.g. worsening of disease-related symptoms, new symptoms suggestive of disease recurrence or progression) or intolerance to therapy occurs.
- Report to and seek advice from the specialist on any aspect of patient care that is of concern.
- Remind patient of the requirement to see her specialist at least every year while taking valproate medicines and arrange for referral as necessary. Refer to specialist if patient does not engage in PPP.
- Report adverse events to the specialist and MHRA; only stop treatment on the advice of the specialist.

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Responsibilities of Patient (The definition 'patient' in this SCA currently refers to a woman of childbearing potential and can be extended to include parent/caregiver/responsible person as appropriate).

- Report to the specialist or GP if they do not have a clear understanding of the treatment or have concerns.
- Contact the GP or specialist urgently if their contraceptive method changes or has failed, or if they have plans to change their contraceptive method, or if they become pregnant or are thinking of becoming pregnant.
- To report any adverse effects to the specialist or GP whilst taking the medicine.
- To be aware of the signs and symptoms of blood or liver disorder or pancreatitis or suicidal ideation or unstable behaviour and seek immediate medical attention if symptoms develop.
- Attend annual reviews with the specialist to complete the ARAF and retain a copy.
- Attend routine reviews for any required monitoring.

1. Summary of condition	Valproate is used to treat epilepsy and bipolar disorder and for migraine prophylaxis (unlic.)	
2. Details of medicine and indication Please state whether licensed or unlicensed (off-label) use. Note that shared care is generally unsuitable for off-label prescribing unless it is a widely recognised use (e.g. included in BNF)	A Shared Care Approach to prescribing valproate is only approved in BSW for these indications: **All forms of epilepsy** **Bipolar disorder and mania/hypomania** Mania and hypomania associated with bipolar disorder; continuation after manic/hypomanic episode where acute mania has responded to valproate. **Migraine prophylaxis (unlic.)** Do not use valproate for migraine prophylaxis for new patients. This is non-formulary, off-label and no longer recommended. Patients currently prescribed valproate for migraine may continue without change until they and their NHS clinician consider it appropriate to stop. Clinicians must review use of valproate at next routine review to explore alternative treatment options.	
3. Pharmaceutical aspects	Route of administration:	Oral.
	Formulation:	Tablet, gastro-resistant tablets, modified release tablet, modified release capsule, modified release granules, oral solution.
	Administration details:	Except in exceptional circumstances, valproate must be dispensed in the manufacturer's original full pack. See MHRA guidance for further information including exceptional circumstances.
	Other important information:	**Dose equivalence and brand prescribing** Semi-sodium valproate and sodium valproate are not bioequivalent and display different characteristics. A 10% dose increase is recommended when switching from valproate semi-sodium valproate to sodium valproate. Depakote® (semi-sodium valproate) and Episenta® / Epival® (sodium valproate m/r) are licensed for treatment of mania. In practice however, generic sodium valproate is commonly used off-label to treat bipolar disorder. Sodium valproate should be used first line before semi-sodium valproate for treatment for bipolar disorder in BSW. Valproate is classified as a category 2 drug. Hence, for epilepsy only, clinical judgement is required when switching between branded original and generic products.

<table>
<tr><td>4. Usual dose and frequency (including details of dose adjustments, e.g. in renal impairment) and duration of therapy</td><td colspan="2">Dose of valproate depends on indication. Consult BNF or BNFC.

Transfer of prescribing to primary care should be no sooner than 3 months and normally after the patient is on a regular dose and with satisfactory investigation results. All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician.

Duration of treatment is life-long or until termination of treatment as advised by the specialist. Avoid abrupt withdrawal; if treatment with valproate is stopped, reduce the dose gradually over at least 4 weeks – refer to specialist for advice.</td></tr>
<tr><td rowspan="2">5. Baseline investigations and initial monitoring to be undertaken by specialist</td><td colspan="2">Baseline investigations</td></tr>
<tr><td colspan="2">• Weight / BMI, FBC and LFTs, U+E and renal function
• A serum pregnancy test is required, before the first prescription is issued, in any woman of childbearing potential, even if individual circumstances mean this is unlikely.</td></tr>
<tr><td rowspan="4">6. Ongoing monitoring requirements to be undertaken by primary care</td><td>Monitoring</td><td>Frequency</td></tr>
<tr><td>LFTs</td><td>During first 6 months of treatment, especially in patients most at risk. Clinical vigilance is most important, see section 7. Severe reported complications have occurred early in treatment and usually in children in treatment for epilepsy.</td></tr>
<tr><td>FBC and clotting screen (including bleeding time and coagulation tests)</td><td>Before surgery or following spontaneous bleeding or bruising.</td></tr>
<tr><td colspan="2">For any woman of childbearing potential, pregnancy testing is required, by primary care, in line with the national Pregnancy Prevention Programme (PPP) if not on continuous highly effective contraception method [see section 12] or if there is any reason to suggest lack of compliance or effectiveness of contraception. Prescribe folic acid 5mg daily immediately and refer back to specialist and maternity/obstetrics service urgently (same day) in case of unplanned pregnancy. Remind the patient not to stop taking valproate medicine in the interim.

For adult patients with bipolar disorder, as part of annual physical health check recommended in NICE CG185 Bipolar disorder: assessment and management:
Weight or BMI, diet, nutritional status and level of physical activity. Cardiovascular status, including pulse and blood pressure. Metabolic status, including fasting blood glucose or glycosylated haemoglobin (HbA1c), and blood lipid profile. Consider referral to dietician or other local services if relevant comorbidities are present (e.g. heart disease, diabetes) or BMI >35.</td></tr>
<tr><td>7. Action(s) to be taken by primary care if abnormal result(s)</td><td colspan="2">• Raised liver enzymes are usually transient. Raised liver enzymes in isolation are not always a good measure. Patients should be assessed clinically and FBC (including platelets) and liver function (including prothrombin time and coagulation tests) monitored until return to normal. Discontinue if abnormal liver function (do not stop if liver enzymes raised in isolation).
• If FBCs and clotting abnormal, discuss with specialist.</td></tr>
<tr><td>8. Cautions and contraindications
Please note this does not replace the Summary of Product Characteristics (SPC)</td><td colspan="2">Cautions
• Use caution in patients with systemic lupus erythematosus (SLE)
• Consider vit D supplementation in those that are immobilised for long periods or who have inadequate sun exposure or dietary intake of calcium.
• Liver dysfunction (including fatal hepatic failure) has occurred in association with valproate usually in first 6 months and usually involving multiple antiepileptic therapy. Raised liver</td></tr>
</table>

and should be read in conjunction with it.	enzymes during valproate treatment are usually transient but patients should be reassessed clinically, and liver function (including prothrombin time) monitored until return to normal - discontinue if abnormally prolonged prothrombin time (particularly in association with other relevant abnormalities). **General contra-indications** • Acute porphyrias; mitochondrial disorders (higher rate of acute liver failure and liver-related deaths); personal or family history of severe hepatic dysfunction; urea cycle disorders. **Special contra-indications relating to valproate teratogenicity [also see section 12]** • Valproate is highly teratogenic. Evidence supports that use in pregnancy leads to neurodevelopmental disorders (approx. 30–40% risk) and congenital malformations (approx. 10% risk). • Valproate must only be used in any woman of childbearing potential, if the conditions of PPP are met and only if other treatments are ineffective or not tolerated, as judged by an experienced specialist. • Contra-indicated in pregnancy for migraine prophylaxis and bipolar disorder; valproate must only be considered for epilepsy if there is no suitable alternative treatment; in such cases, access to counselling about the risks should be provided and a Risk Acknowledgement Form signed by both specialist and patient. • Contra-indicated for migraine prophylaxis for **any** new patients. This is off-label and no longer supported on BSW formulary. Existing patients to be assessed at next routine specialist review.
9. Significant medicine and food interactions and management For a comprehensive list, consult the BNF or Summary of Product Characteristics (SPC)	Some 'severe' interactions, as categorised by BNF summarised below. See BNF or SPC for comprehensive list of drug interactions with valproate. • **Anti-seizure medicines**: concomitant use of multiple anti-seizure medicines may increase risk of teratogenicity. • **Antipsychotics, monoamine oxidase inhibitors, antidepressants, and benzodiazepines** – valproate may potentiate effect of other psychotropic medicines. • **Oestrogen-containing medicines**, including contraceptives – may increase clearance of valproate and reduce efficacy. • **Acetazolamide, guanfacine, Cytochrome P450 inhibitors** e.g. erythromycin, fluoxetine, cimetidine may increase exposure to valproate and/or risk valproate toxicity. • **Bupropion, lamotrigine, nimodipine, nortriptyline, primidone, propofol** – exposure increased by valproate • **Ritonavir, carbapanem antibiotics**, e.g., ertapenem, imipenem, meropenem reductions in valproate levels, avoid where possible. • **Phenobarbital, phenytoin and fosphenytoin** – levels of either/both medicines may be altered. • **Hepatotoxic medicines, cannabidiol, pivmecillinam, quetiapine** – increased risk of adverse effects. • **Topiramate** – increased risk of toxicity when co-administered with valproate, monitor for signs and symptoms of encephalopathy or hyperammonaemia • **Highly protein bound drugs**, e.g. aspirin – may displace valproate, risking toxicity • **Less strongly protein bound drugs**, e.g. warfarin – may be displaced by valproate, with possibility of increased therapeutic effects or toxicity.

<table>
<tr><td rowspan="2">10. Adverse effects and management
Include details of incidence, identification, importance and management.</td><td>Adverse Effect</td><td>Action to be taken if detected</td></tr>
<tr><td colspan="2">Report serious adverse reactions via MHRA Yellow Card scheme www.mhra.gov.uk/yellowcard
For information on incidence of ADRs see relevant summaries of product characteristics</td></tr>
<tr><td></td><td>• Blood dyscrasias. Symptoms include spontaneous bruising/bleeding, purpura, sore throat, fever, or malaise.</td><td>• Continue valproate medicine and discuss with specialist team urgently (same day). FBCs, LFTs and coagulation screen are indicated; discuss most appropriate route with specialist team.</td></tr>
<tr><td></td><td>• Liver dysfunction. Symptoms include asthenia, malaise, jaundice, anorexia, oedema, lethargy, drowsiness, vomiting, abdo pain, seizure recurrence.</td><td>• Repeat LFTs and coagulation screen and discuss with specialist team urgently (same day). Stopping valproate medicine may be indicated while waiting for results, particularly if strong suspicion that worsening seizures are due to hepatic dysfunction.</td></tr>
<tr><td></td><td>• Gastrointestinal disorder. Symptoms of pancreatitis include acute abdominal pain, nausea, or vomiting.</td><td>• Refer for urgent hospital admission if suspected acute pancreatitis, for further management. Do not delay admission by taking blood samples or ordering imaging in primary care.</td></tr>
<tr><td></td><td>• Psychiatric disorder. Suicidal ideation or behaviour.</td><td>• Refer for urgent psychiatric assessment via local pathways e.g. crisis or specialist teams, if appropriate. Notify specialist team. Do not stop valproate medicine.</td></tr>
<tr><td>11. Advice to patients and carers
The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review but the ongoing responsibility for providing this advice rests with both the GP and the specialist.</td><td colspan="2">All prescribers must ensure that any female child or any woman who can become pregnant, even if individual circumstances mean this is unlikely are informed of and understand:

▪ the risks associated with valproate during pregnancy
▪ the need to comply with highly effective contraception (see section 12) and to contact the GP or specialist urgently if their contraceptive method changes or has failed, or if they have plans to change their contraceptive method or are planning a pregnancy or becomes pregnant,
▪ the need for regular (at least annual) review of treatment.

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?
○ 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.

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</td></tr>
</table>

12. Conception, contraception, pregnancy and breast feeding It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review but the ongoing responsibility for providing this advice rests with both the GP and the specialist.	**Teratogenicity** Valproate is highly teratogenic (known risk of birth defects and neurodevelopmental disorders following use in pregnancy). It should only be prescribed for women of childbearing potential in exceptional circumstances in line with Annual Risk Acknowledgement Form (ARAF) and this SCA. **Relevant to Males prescribed valproate** Valproate may cause infertility in men, with some toxic effects observed on the testes in animal studies, though its significance is unclear for humans. In September 2024, the MHRA advised men taking valproate and their partners to use effective contraception because of new data suggesting a potential small increased risk of neurodevelopmental disorders in children if valproate is used by a father around the time of conception. Further advice is available in this Drug Safety Update. **Highly effective contraception** Supply of contraception should be provided in a timely manner. **Highly effective contraception** is considered to be user independent methods such as: - long acting reversible contraceptives (LARC), - copper intrauterine device (Cu-IUD), - levonorgestrel intrauterine system (LNG-IUS), - progestogen only implant (IMP) and - female sterilisation. all of which have a failure rate of less than 1% with typical use. Progestogen-only injections have a typical-use failure rate of 6%, but this may be due to repeat injections being administered late. Progestogen-only injections may be considered as highly effective if repeat injections are documented as having been administered on schedule by a healthcare professional. Individual circumstances should be evaluated when choosing the contraception method, involving the patient in shared decision making to guarantee engagement and compliance. Pregnancy tests may not detect an early pregnancy that has occurred after unprotected sex in the preceding 3 weeks. Therefore, repeat pregnancy test 3 weeks after starting a new contraceptive method if there was any risk of pregnancy at the start of the contraceptive method, even if the first test was negative. Further info in MHRA Guide for Healthcare Professionals Information on the risks of Valproate use in girls (of any age) and women of childbearing potential (Epilim, Depakote, Convulex, Episenta, Epival, Kentlim, Orlept, Sodium Valproate, Syonell, Valpal, Belvo & Dyzanti, and FSRH CEU Statement: Contraceptive Choices and Sexual Health for Transgender and Non-binary People. **For Women Not At Risk of Pregnancy** An individualised risk-based decision must be undertaken by the specialist for women who are not at risk of pregnancy for health-related, physical or personal reasons such as women who have had a hysterectomy or tubal ligation, a woman in a long-term monogamous relationship with a vasectomised male partner, women in same sex relationships not planning pregnancy or a transgender woman who does not have a uterus. The reason must be documented on the ARAF, in the patient records and relevant clinical correspondence. If the reason is *permanent*, annual specialist review from the perspective of the regulations per se should not be necessary but may be indicated for the underlying condition. If the reason is *not considered permanent*, the woman needs to be fully aware of the high likelihood of serious harm to the child if she should conceive and attend for annual specialist review and completion of the ARAF, in line with the PPP. **Breastfeeding** Present in milk—risk of haematological disorders in breast-fed newborns and infants – seek specialist advice.

13. Specialist contact information	**Contact named responsible clinician using contact details included in clinic letter or via cinapsis. Alternative general contact details provided below**: **Neurology** • Royal United Hospital, Bath ruh-tr.adultepilepsynurses@nhs.net • Salisbury Foundation Trust sft.admin.neurology@nhs.net • Great Western Hospital, Swindon gwh.neurologyrefs@nhs.net **Psychiatry** • AWP Switchboard: 01225325680 **Contraception and Sexual Health** • Royal United Hospital, Bath ruh-tr.sexualhealthclinic@nhs.net • Salisbury Foundation Trust shc-tr.Sexualhealth@nhs.net • Great Western Hospital, Swindon gwh.swish@nhs.net
	BSW ICS Medication Safety Officer (MSO) contact emails: • BSW ICB: bswicb.prescribing@nhs.net • Royal United Hospital, Bath: ruh-tr.BATHmso@nhs.net • Great Western Hospital, Swindon: gwhmedsafety@nhs.net • Salisbury Foundation Trust: sft.mso@nhs.net
	Transgender men and non-binary (assigned female) people • This guidance around use of valproate in female patients of childbearing potential also applies to transgender men (assigned female at birth) and non-binary (assigned female at birth) people who have **not** undergone hysterectomy (i.e. who still have a uterus) or bilateral oophorectomy. N.B. treatment with testosterone and gonadotrophin releasing hormone analogues cannot be relied on for contraceptive protection.
14. References, useful resources and additional information	• BNF Online https://bnf.nice.org.uk/ and BNFC online https://bnfc.nice.org.uk/ • Summary of Product Characteristics for Valproatehttps://www.medicines.org.uk/emc • SPS Medicines Monitoring Tool https://www.sps.nhs.uk/home/tools/drug-monitoring/ • MHRA. Collection Valproate safety measures. Available from: https://www.gov.uk/government/collections/valproate-safety-measures?utm_medium=email&utm_campaign=govuk-notifications-topic&utm_source=1831cba2-cc84-4d38-b2d6-cd505f869ec8&utm_content=immediately • ARAF for Female Patients. https://mhra-gov.filecamp.com/s/i/6iqrRqc0zoFgeEo7 • RAF for male patients. https://mhra-gov.filecamp.com/s/i/bEnPD49yZtHsXp3M • MHRA guidance – Valproate use by women and girls • NHSE Decision support tool: is valproate the right epilepsy treatment for me? • AWP Patient information leaflets on valproate • FSRH CEU Statement: Contraceptive Choices and Sexual Health for Transgender and Non-Binary People • SPS Specific medicine switches for solid dose and liquid formulations Online https://www.sps.nhs.uk/articles/specific-medicine-switches-for-solid-dose-and-liquid-formulations/ • MHRA Guide for Healthcare Professionals Information on the risks of Valproate use in girls (of any age) and women of childbearing potential (Epilim, Depakote, Convulex, Episenta, Epival, Kentlim, Orlept, Sodium Valproate, Syonell, Valpal, Belvo & Dyzantil) https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/950802/107995_Valproate_HCP_Booklet_DR15_v07_DS_07-01-2021.pdf

	• MHRA DSU 5th September 2024. Valproate use in men: as a precaution, men and their partners should use effective contraception. https://www.gov.uk/drug-safety-update/valproate-use-in-men-as-a-precaution-men-and-their-partners-should-use-effective-contraception • Pan College Guidance Document on Valproate Use in Women and Girls of Childbearing Years, Judy Shakespeare FRCGP, Sanjay M Sisodiya FRCP, on behalf of the Royal College of General Practitioners and Association of British Neurologists and Royal College of Physicians; Version 1, 29th March 2019. Available from: https://www.rcog.org.uk/guidance/browse-all-guidance/other-guidelines-and-reports/valproate-use-in-women-and-girls-of-childbearing-years/ • **All local SCAs should be read in conjunction with** NHS England: Responsibility for Prescribing Between Primary & Secondary/ Tertiary Care. Ref 07573, Version 1.0, Published January 2018. Accessed via: https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/

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