Safer prescribing of sodium valproate and valproic acid (valproate) (with childbearing potential) in Primary Care

Background

The Area Prescribing committee (APC) recommends sodium valproate (all brands and salts) for women of childbearing potential for the treatment of epilepsy or bipolar disorder, in line with the Medicines and Healthcare products Regulatory Agency (MHRA).

The MHRA has published a set of resources, the valproate toolkit, to emphasise the need to avoid the use of valproate in girls and women of childbearing potential and warn women of the very high risks to the unborn child of valproate in pregnancy (see below Useful links)

Whilst the use of valproate outside of the licensed indications has not been considered by APC, any use of valproate in women of childbearing potential irrespective of indication would be subject to the Pregnancy Prevention Programme (PPP). Link to MHRA Pregnancy Prevention Programme

Healthcare professionals who seek to prescribe valproate for their female patients must make sure the patient is enrolled in the PPP. This includes the completion of a signed risk acknowledgement form (ARAF) when their treatment is reviewed by a specialist, at least annually.

- Review the patients record to ensure they are under a specialist and have an annual risk acknowledgement form which is in date.
- Ensure this is coded on EMIS (See Appendix 4). Patient should also be on appropriate contraception if applicable.

If any of this information is missing the practice must ensure this is followed up with the specialist.

The Care Quality Commission (CQC) guidance – High risk medicines: valproate states that GPs MUST:

- Identify and review all female patients on valproate, including when it is used outside the licensed indications (off-label use) - for example migraine prophylaxis.
- Provide patient information materials every time the patients attend their appointments or receive their medicines.
- Check they have been reviewed by a specialist in the last year and are prescribed appropriate contraception.

Warnings on use of valproate during pregnancy for bipolar disorder or for epilepsy

Prescribing valproate to a woman of childbearing potential without the pregnancy prevention programme conditions being fulfilled is contraindicated and represents an unlicensed use of the drug. Use of valproate during pregnancy for bipolar disorder, and during pregnancy for epilepsy (unless there is no suitable alternative treatment), are both unlicensed. This is the case even when treatment is based on an informed choice made by the patient.

Prescribers are expected to follow the General Medical Council's guidance in "Good practice in prescribing and managing medicines and devices". You must document in the patient's clinical record your reason for unlicensed use, that you have informed the patient of the unlicensed use and its associated risk.

Reference: Booklet for Healthcare professionals: Valproate in women with childbearing potential

The Medicines for Women's Health Expert Advisory Group of the Commission on Human Medicines has developed an aide-memoire table to provide guidance to prescribers of medicines with teratogenic potential on the frequency of pregnancy testing needed to avoid exposure in pregnancy during treatment, depending on the chosen contraceptive method which provides a summary of the pregnancy testing advice for the most common contraceptive methods.

Further information is available on the Surrey PAD including shared care agreements for differing conditions, links to national guidelines and MHRA advice at Surrey PAD Sodium valproate (with childbearing potential)

Produced by Celia Houlihan on behalf of Surrey Heartlands Medicines Safety Committee
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Flow diagram: Summary on how to manage patients of childbearing potential on valproate within primary care.

New Patients

The specialist should prescribe a minimum of 1 month at initiation before transfer of care is requested with the patient's primary care prescriber. Primary care should only prescribe once the patient is stable, shared care has been received and signed ARAF/PPP in place

NO

If either are absent [without very detailed explanation as to why not] communicate back to consultant urgently requesting this information to enable prescriber to take over prescribing responsibility.

Existing Patients

Run report within prescribing system (See Appendix 1) to identify women of childbearing age on valproate medication

Use the Ardens template to do annual review (Appendix 2)

Ensure patient is on highly effective contraception if appropriate and document on clinical system. If prescribed outside primary care add to Hospital issue only section of medication list. *(Ref: aide-memoire table)*

Has the patient had an annual specialist review including provision of Annual Risk Acknowledge Form (ARAF) completed?

Y/N

NO

Send referral to request an ARAF using the auto-populated referral letter on clinical system (Appendix 3) and use appropriate SNOMED code (Appendix 4)

YES

Once received, code in clinical system ARAF complete (Appx 4)

Periodically check all patients to ensure all patients on valproate have been reviewed, an ARAF filled out and on highly effective contraceptive

If on PPP but planning a family

OR

If PPP not in place and possibly pregnant

Refer URGENTLY to consultant

Prescriber needs to undertake annual review of patients to check the patient

- Understands the risks of valproate use in pregnancy
- Adheres to PPP with one highly effective or two effective contraceptive methods in place
- Have a specialised review annually to discuss risks
- Report any suspected adverse reactions associated with valproate, including adverse pregnancy outcomes, to the **Yellow Card Scheme**

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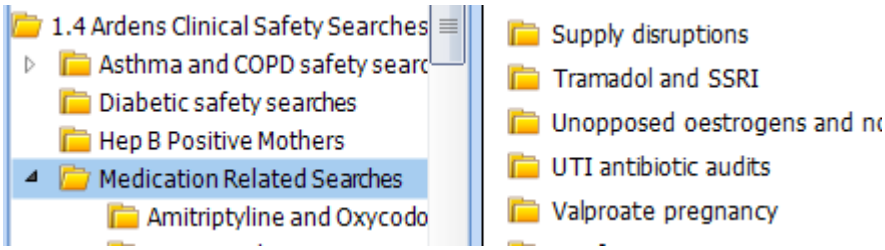
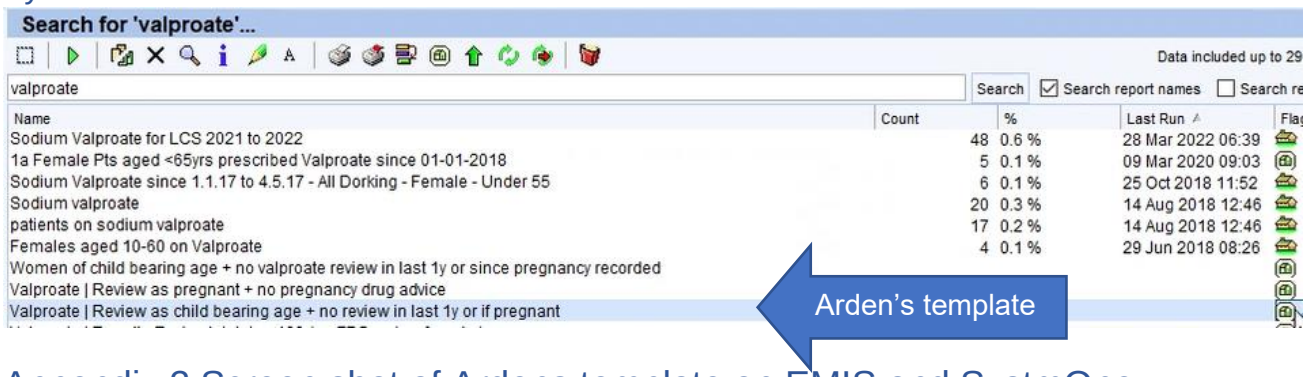
Appendix 1. Screen shot of Arden's search on EMIS and SystmOne

EMIS

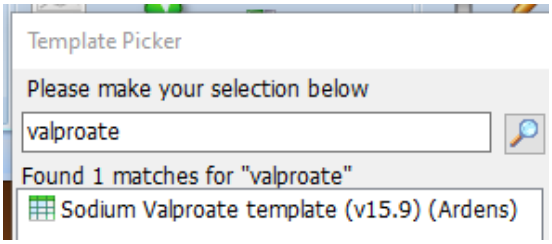


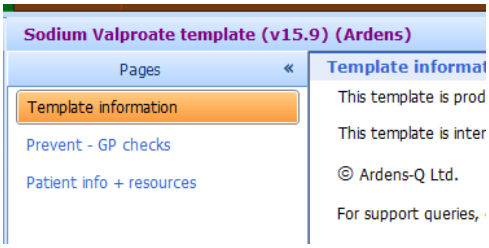
SystmOne



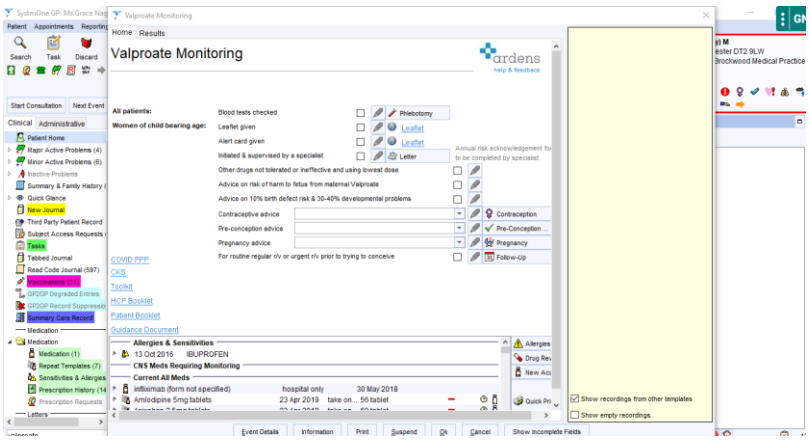
Appendix 2 Screen shot of Ardens template on EMIS and SystmOne

EMIS





SystmOne



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Appendix 3 Auto-populated referral letter on clinical system to request ARAF


GP Referral Form for Annual Review


SABP GP Referral cform for Sod Valp S´

Appendix 4 Valproate Project: SNOMED Codes

NHS Digital have released SNOMED codes for valproate. It is recommended that all practices use these codes to support the recording of a patients Annual Risk Acknowledgement Form status. These codes can be used for **ALL** patients on valproate for any condition, licensed or unlicensed, not just mental health.

• **Valproate Annual Risk Acknowledgement Form completed** (situation)
SCTID:1366401000000107
Valproate Annual Risk Acknowledgement Form completed (situation)
Valproate Annual Risk Acknowledgement Form completed
Valproate ARAF (Annual Risk Acknowledgement Form) completed
• **Referral for completion of Valproate Annual Risk Acknowledgement Form** (procedure)
SCTID: 1366381000000107
Referral for completion of Valproate Annual Risk Acknowledgement Form (procedure)
Referral for completion of Valproate Annual Risk Acknowledgement Form
Referral for completion of Valproate ARAF (Annual Risk Acknowledgement Form)

Advice for Healthcare Professionals: Please ensure the correct codes are used when entering information onto patients' notes

Additional documents


Valproate key messages SABP FINA


107995_Valproate_Patient_Booklet_v05_l


Risk-acknowledgment.pdf

Useful links

- Annual Risk Acknowledgement Form
- Booklet for Healthcare professionals: Valproate in women with childbearing potential
- Patient Card
- Patient Guide: What women and girls need to know about valproate

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