prevent
valproate pregnancy prevention programme

Medication Safety Series: MSS 13

Valproate Medicines Safety Measures including Pregnancy Prevention Programme

NEVER prescribe valproate:
- if there is child-bearing potential without a PPP in place
- for migraine or bipolar disorder in pregnancy

NHS
Tees, Esk and Wear Valleys
NHS Foundation Trust

Valproate Safety Measures

See Guide for Healthcare Professionals for full details

Initiation:
- Valproate should not be initiated in patients aged under 55 years unless two specialist prescribers independently consider and document (using the forms linked in this alert) that there is no other effective or tolerated treatment, or that there are compelling reasons that the reproductive risks do not apply
- Advice for male patients on valproate to use contraception and visual risk communication diagram to be used by a healthcare professional when counselling on the risks
- Valproate is contraindicated where there is childbearing potential, unless a Pregnancy Prevention Programme (PPP) is in place.
- There is an absolute contraindication on use of valproate for bipolar disorder (and other non-epilepsy indications) during pregnancy.
- If a patient becomes pregnant, treatment with valproate must be discontinued and switched to another treatment.

Annual review:
- An annual review is required where there is child-bearing potential. The next annual review for the patient requires two specialist prescribers to agree that continuation is appropriate, but subsequent reviews only require one.

Specialist prescriber definition: a prescriber working with TEWV that is experienced in managing patients with bipolar disorder. The second specialist prescriber can be a named representative following an MDT discussion. Note: the named specialist prescribers cannot be a foundation doctor (or similar level doctor) and must be level 2 or above if a non-medical prescriber.

Shared decision making with patients of child-bearing potential can be supported by Bipolar disorder: is valproate the right treatment for me?

Risk Acknowledgement Forms

The appropriate form* (below) must be downloaded, completed with the patient, and scanned / saved into CITO. A copy must be given to the patient and sent to the GP. See second page for further advice.
- Female Patients: Risk Acknowledgement Form (New Starter & Review)
- Male Patients: New Starter Risk Acknowledgement Form

Each step on the form should be completed in full.
Allowed exemptions can be noted in step 1 of the risk acknowledgment form.
*Please note these nationally required forms do not use inclusive gender language.

Specialist Prescriber Responsibilities

- Discuss the risks with the patient / responsible person and complete a Risk Acknowledgement Form as above.

Where there is childbearing potential:
- Exclude pregnancy (by a pregnancy test) before initiation
- Ensure the need to have, and comply with, highly effective contraception throughout the entire duration of treatment, is understood. Please see the supporting documentation for further information.
- Perform an **annual review** with the patient to assess continuing need and to complete a new risk acknowledgement form if prescribing continues.
- Review and switch treatment, within days of referral, if there is an unplanned pregnancy
- Review and switch treatment for patients planning to become pregnant
- Recording the key points of the discussion in electronic care record including completion of the Risk Acknowledgement form
- Where applicable for new patients: send a copy of the shared care document to the GP with the transfer of prescribing request

Prescribing Valproate: Dispensing Quantities

Unless there are exceptional circumstances, valproate-containing medicines must be dispensed (by community pharmacies & TEWV dispensaries) in the manufacturer's original full pack (tablets packs are 30 or 100). Exceptional circumstances apply if an individual risk assessment is carried out (this should form part of the individual's safety summary) and would be appropriate in the following circumstances:
- **Discharge / Out-Patient Prescriptions:** where there is a risk of self-harm and it is appropriate to limit supplies (e.g. to 7 days). The prescription should be annotated *"risk assessment in place **please supply exact quantity** requested".* [If the prescription is not annotated the pharmacy are required to dispense the nearest full pack.]
- Valproate should not normally be supplied in a monitored dosage system (MDS) due to stability. If an MDS is essential a risk assessment must be in place and communicated to the dispensing pharmacy.

An individual risk assessment is not required for **self-admin in secure in-patient services or leave prescriptions.** These will be dispensed by TEWV dispensaries in exact quantities under an overarching risk assessment agreed by D&T.

Supporting documentation

- Patient Guide & Patient Card
- NHS Valproate bipolar disorder decision tool
- Pregnancy testing and contraception
- MHRA Guidance
- Drug Safety Update – February 2025 with infographics

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Valproate Prescribing – Safety requirements

prevent valproate pregnancy prevention programme

NHS Tees, Esk and Wear Valleys NHS Foundation Trust

Female*

Age > 55 years

Complete usual regular/annual treatment review.
Shared care does not apply

Age from Menarche to 55 years

Existing valproate prescription

Permanent reason PREVENT does not apply e.g. hysterectomy

Complete usual regular/annual treatment review.
Shared care does not apply

Complete section 1 of ARAF

New / restarted valproate prescription

PREVENT applies – complete ARAF annually
(Shared care applies)
(2 specialists required for ALL new initiations & for first annual review after Jan 2024♦)

♦ National recommendation - all current patients to whom PREVENT applies should have one ARAF completed by 2 specialists

Male*

(of any age who may father children; shared care does not apply)

Existing valproate prescription

Complete usual regular/ annual treatment review

Reproductive risks apply

Ensure patient is aware of the risks of fathering children whilst taking valproate: offer contraceptive advice for patient & female partner; refer for specialist advice if planning a family in next year & offer advice on sperm donation as appropriate.

New / restarted valproate prescription

Age > 55 years

Complete usual regular/ annual treatment review

Reproductive risks apply

Ensure patient is aware of the risks of fathering children whilst taking valproate: offer contraceptive advice for patient & female partner; refer for specialist advice if planning a family in next year & offer advice on sperm donation as appropriate.

Age < 55 years

Complete section 1 of RAF

Reproductive risks DON'T apply● – save form in notes

Reproductive risks apply

Complete rest of RAF prior to prescribing (Agreed by 2 specialists)

Ensure patient is aware of the risks of fathering children whilst taking valproate: offer contraceptive advice for patient & female partner; refer for specialist advice if planning a family in next year & offer advice on sperm donation as appropriate.

● e.g. patient is permanently infertile

*National literature uses the terms male & female.
The female algorithm also applies to trans-males
The male algorithm applies to anyone who can biologically father children

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