

Valproate – Information for Primary Care – GPs/Community Pharmacy

There are well documented significant risks of serious harm to a baby after exposure to valproate in pregnancy. A number of new additional measures have been introduced by the MHRA aiming to ensure valproate is only used if other treatments are ineffective or not tolerated. Also that any valproate use in women of childbearing potential must be in accordance with the Pregnancy Prevention Programme (PPP/PREVENT).

[NPSA alert](#) relating to Valproate prescribing states all Health Boards must put the following requirements in place:

- 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.
- 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. Subsequent annual reviews require only one specialist signature, unless the patient's situation changes.

As per the NPSA requirements NHS Grampian has set up a Short Life Working Group to consider local guidance and protocols to ensure all NPSA/MHRA regulatory requirements regarding prescribing of valproate are met.

What does this mean for GP Practice:

- GP practices should continue to prescribe valproate for current patients
- Check that females <55 are aware of valproate patient resources including the [patient guide](#) regarding valproate and the requirements and importance of specialist annual reviews.
- Specialist services are responsible for completion of annual risk assessments (ARAFs) for all female patients, <55 years of age. Completed forms will be shared with GP practices, a copy should be held in the patient records. (A form will also be completed for new males requiring treatment with valproate – for males this is only done at the point of initiation by the specialist.)
- NHSG approval has been obtained to allow sharing of details of female patients, <55 years of age, prescribed valproate with secondary care specialities – neurology, paediatric neurology, learning disabilities and psychiatry. This will be cross checked against their current active patient lists.
- GP Practices may be asked for additional information regarding specific patients if they are currently not known to secondary care specialist services. This is necessary as the specialist service must complete an ARAF for all woman <55 years of age prescribed valproate and ensure they are compliant with PPP/PREVENT, unless there is a compelling reason that this is not necessary. Information may include diagnosis, initiation, contraception and/or menopause/hysterectomy status.
- GP practices cannot complete the ARAF documentation.

- Prescribers should ensure all female patients < 55 are linked with the appropriate specialist service, have an ARAF in place and remain on effective contraception (preferably highly effective, user independent form such as IUD or implant or two complementary forms of contraception including a barrier method should be used).
- Primary care must not prescribe /initiate valproate for new patients (male or female) without a specialist service recommendation and completed risk assessment form, with dual signatures. Dual signatures are required for all males and females being initiated on valproate.
- If any new female patients, < 55 registering with a practice are currently prescribed valproate the GP practice should confirm the diagnosis, and speciality the patient should be linked with. Patient consent should be obtained to share this information with the appropriate specialist service to ensure ongoing specialist review and ARAF is completed. This is particularly important for patients moving into the Grampian area.

What does the mean for Community Pharmacy:

- Pharmacists do not require to see or confirm that an annual risk assessment form (ARAF) is in place prior to dispensing valproate. All that is required is a valid, signed prescription. Prescriptions require to be signed by one prescriber.
- Valproate must be dispensed in original packs, ensuring the patient/carer is provided with the Patient Information Leaflet (PIL) and patient card.
- Pharmacies will have received new versions of patient cards. They should to remove old cards, currently attached to packs, and supply a new card at each dispensing. This is an interim measure until manufactures supply new cards attached to packaging.
- Dispensing of valproate in alternatives to original packs should only be undertaken following a risk assessment, documenting why this is required for the patient. It must be ensured the patient receives a PIL and patient card at each dispensing.
- Discuss risks in pregnancy when dispensing valproate medicines and ensure they have access to the [patient guide](#).

Further information will be shared as necessary, should you have any queries regarding the management of valproate for a specific patient please discuss this with their speciality in the first instance.

Resources:

[Valproate safety measures - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

Lesley Coyle
Associate Director of Pharmacy
Medicines Management Team
Pharmacy & Medicines Directorate

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