

New Valproate safety measures – January 2024

From the 31st of January 2024, new regulatory measures were put in place to further reduce the known harms from valproate, including the significant risk of serious harm to the baby if taken during pregnancy and the risk of impaired fertility in males.

New measures (responsibility of specialist clinician)

- Valproate **must not** be started in new male or female patients younger than 55 years, unless 2 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.
- **All women and girls of childbearing age currently taking valproate** will need a second opinion signature at their next annual specialist review if valproate is to continue. This will be documented on the new Annual Risk Acknowledgment form (ARAF).

Please note: There are no regulatory changes for the prescribing of valproate in male patients currently taking valproate.

IMPORTANT: Patients should not stop taking valproate without advice from their specialist

Actions for ALL Primary Care Healthcare Professionals:

- Review the new measures and updated safety and educational materials available [Valproate \(Belvo, Convulex, Depakote, Dyzantil, Epilim, Epilim Chrono or Chronosphere, Episenta, Epival, and Syonell ▼\): new safety and educational materials to support regulatory measures in men and women under 55 years of age](#)

These include

- [Healthcare Professional 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 guide](#): 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.
- [Annual 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.
- New [Risk Acknowledgement Form for male patients starting valproate](#): Used to support and record the discussion between the patient and specialist prescriber of the risks associated with valproate in males when starting treatment with valproate and to record the decision of the countersigning specialist. This is only to be completed at initiation of valproate.
- [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.
- [Warning stickers](#): To be added to packaging of medicine in exceptional circumstances where the original pack cannot be dispensed.

Actions for General Practitioners

- Check if there are any male or female patients prescribed valproate in your practice
 - Ensure that the patient is under the care of an appropriate specialist for their treatment with Valproate – it is helpful to have the indication (s) linked to the prescribing of valproate
 - Refer any new patient to a specialist prescriber for diagnosis and initiation of treatment
 - Arrange to see each female patient after specialist review and if on valproate, ensure that the patient
 - has the patient guide and a copy of the signed ARAF is filed, and coded, in the patient's medical records
 - is using effective contraception and understands the need to comply with effective contraception throughout treatment with valproate
 - is reminded to contact their GP immediately if they suspect there has been a problem with their contraception, or if they may be pregnant
 - Female patients who are pregnant should not stop valproate and should be referred to their specialist prescriber to be seen urgently (within days)
 - Female patients who are planning to become pregnant should be referred to their specialist. They should not stop contraception or valproate unless told to by their specialist
 - Remind female children using valproate, and/or their parent/carer, to contact their GP once she reaches menarche. Refer the patient back to the specialist
 - Remind all female patients that they will need to see their specialist prescriber at least annually whilst taking valproate and arrange the referral annually.
 - Ensure that completion of ARAF forms and Pregnancy Prevention is recorded using SNOMED codes, or equivalent

	SystemOne code	SNOMED Concept ID
Pregnancy Prevention Programme started <i>To be used when an ARAF is received from secondary care and ongoing annual reviews are required</i>	Y2f16	1129771000000103
Pregnancy Prevention Programme declined <i>To be used the patient has been referred to secondary care, was given an appointment for ARAF completion but did not attend</i>	Y2f17	1129801000000100
Pregnancy Prevention Programme not needed <i>To be used when an ARAF is received from secondary care and ongoing annual reviews are not needed, for example, a patient who is of childbearing age but has had a hysterectomy</i>	Y2f18	1129791000000104
Pregnancy Prevention Programme discontinued	Y2f19	1129841000000102
Did not attend Pregnancy Prevention Programme	Y2f1a	1129831000000106
Pregnancy Prevention Programme declined by parent	Y2f1b	1129821000000109
Pregnancy Prevention Programme declined caregiver	Y2f1c	1129811000000103
Valproate Annual Risk Acknowledgement Form completed <i>To be used when Valproate ARAF received from secondary care</i>	Y362e	1366401000000107
Referral for completion of Valproate Annual Risk Acknowledgement Form <i>To be used when a referral has been made from primary care to secondary care</i>	Y38a6	1366381000000107

There are also SNOMED codes to describe biological exemptions from the Pregnancy Prevention Programme (PPP), such as hysterectomy, and codes for the insertion of, or presence of IUD/S or implant that can also be used to enhance record keeping and facilitate audit.

- Continue to prescribe Valproate after specialist initiation.

Actions for Practice Nurses

- Provide counselling on methods of contraception and pregnancy planning.
- Provide information about the risks of using valproate during pregnancy.
- When a patient consults for pregnancy, urgently refer the patient to be seen (within days) by their specialist prescriber.

Actions for Community Pharmacists

- Ensure the Patient Card is provided every time valproate is dispensed to a female patient.
- Ensure the patient has received the Patient Guide or knows they can access it online using the QR code on the package leaflet.
- Confirm with female patients that they have been made aware
 - of the risks in pregnancy.
 - to always use effective contraception and to see their GP to be urgently referred to their specialist, should they be planning a pregnancy.
 - NOT TO STOP valproate and to immediately contact their GP for an urgent referral to their specialist in case of suspected pregnancy.
- Dispense valproate in the original package. If this is not possible for the patient, then a risk assessment must be undertaken.
 - In exceptional circumstances, where a patient needs to receive their medication in different packaging such as a Monitored Dosage System, ALWAYS provide a copy of the package leaflet, the patient card and add a valproate warning sticker to the outer box.
- If a female patient reports that they
 - are not continuously taking an effective method of contraception,
 - are not aware of the need for contraception or
 - have not been seen by their specialist in the past year,

dispense their medicine and refer them to their GP.

A South West London multidisciplinary working group is meeting regularly to discuss these changes. Information will be shared with all Healthcare professionals when available.