

Valproate ▼: Pregnancy Prevention Programme

This medicine will be referred to as valproate throughout this poster and covers the brands Epilim, Depakote, Convulex, Episenta, Epival, Sodium Valproate, Syonell, Belvo & Dyzantil.

(Sodium valproate, valproic acid, valproate semisodium)



REMINDER

Valproate must be prescribed and dispensed according to **prevent** - valproate Pregnancy Prevention Programme.

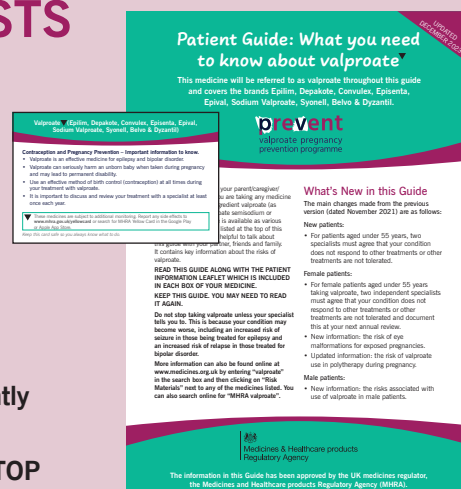
Valproate should not be prescribed to female patients aged under 55 years unless two specialists independently consider and document that there is no other effective or tolerated treatment. This is documented in the annual risk acknowledgement form for female patients (ARAF).

Valproate has a high teratogenic potential and children exposed *in utero* to valproate have a high risk for congenital malformations (11%) and neuro-developmental disorders (up to 30–40%) which may lead to permanent disability.

IMPORTANT ACTIONS FOR PHARMACISTS

Whenever you dispense valproate to any female patient:

- ✓ Detach the Patient Card from the carton and give it to the patient every time valproate is dispensed.
- ✓ 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.
- ✓ Confirm with female patients that they have been made aware to always use effective contraception and to see their General Practitioner (GP) to be urgently referred to their specialist, should they be planning a pregnancy.
- ✓ Confirm with female patients that they have been made aware to NOT TO STOP valproate and to immediately contact their GP for an urgent referral to their specialist in case of suspected pregnancy.
- ✓ Dispense all valproate prescriptions in the original packaging.
- ✓ 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 and a Patient Card, and ALWAYS add a valproate warning sticker to the outer box.



See the Guide for Healthcare Professionals and Summary of Product Characteristics for further information.

Copies of the valproate pharmacy materials (valproate warning sticker, valproate Patient Guide, valproate HCP Guide, valproate Patient Card and valproate Poster) can be ordered from Sanofi Medical Information on:

0800 035 2525 Or by emailing UK-MedicalInformation@sanofi.com

Copies of the materials can also be downloaded from

www.medicines.org.uk

Enter “valproate” in the search box and then click on “Risk Materials” next to any of the medicines listed.

CALL FOR REPORTING

▼ These medicines are subject to additional monitoring. This will allow quick identification of new safety information. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.