FOR DISPENSARY USE ONLY

prevent
valproate pregnancy prevention programme

Valproate▼: Pregnancy Prevention Programme and Reproductive Risks in Males

This medicine will be referred to as valproate throughout this poster and covers the brands Epilim, Depakote, Alprolep, Belvo, Convulex, Dyzantil, Episenta, Epival, Syonell & Sodium Valproate (Crescent, Desitin, Strandhaven/Somex, Wockhardt).

(Sodium valproate, valproic acid, valproate semisodium)



WARNING FOR WOMEN AND GIRLS

REMINDER

Valproate must be prescribed and dispensed to female patients 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.

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.

Children of mothers exposed to valproate during pregnancy may also experience lower weight at birth for the gestational age.

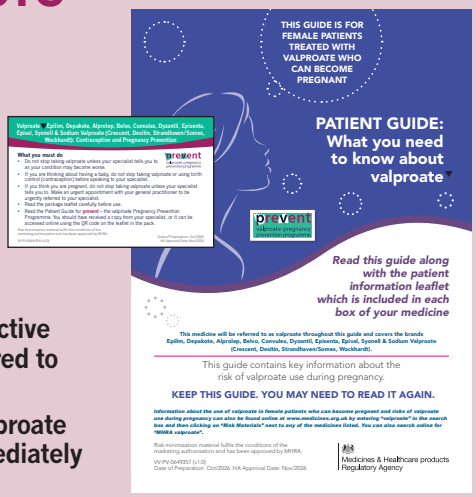
Valproate should not be initiated in male patients aged under 55 years, unless two specialists independently consider and document that there is no other effective or tolerated treatment.

There is a possible risk of neurodevelopmental disorders in children born to male patients treated with valproate in the 3 months prior to conception.

IMPORTANT ACTIONS FOR PHARMACISTS

Whenever you dispense valproate to any 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 the female Patient Guide or male Patient Guide as appropriate 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 all 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 all patients that they have been made aware NOT TO STOP valproate without consulting their specialist. Additionally, female patients should immediately contact their GP for an urgent referral to their specialist in case of suspected pregnancy.**
- ✓ **Confirm with male patients that they have been made aware of the potential risks and the precautionary advice for them and their female partner to consider effective contraception.**
- ✓ **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.**



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

Copies of the valproate pharmacy materials (female Patient Guide, male Patient Guide, HCP Guide, Patient Card and Pharmacy 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.

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Risk minimisation material fulfils the conditions of the marketing authorisation and has been approved by MHRA.