

Valproate ▼: Pregnancy Prevention Programme

Epilim, Depakote, Convulex, Episenta, Epival,
Kentlim, Orlept, Sodium Valproate, Syonell,
Valpal, Belvo & Dyzantil.



**WARNING FOR WOMEN
AND GIRLS**

REMINDER

Valproate must be prescribed and dispensed according to the Valproate Pregnancy Prevention Programme.

Valproate should not be used in female children and women of childbearing potential unless other treatments are ineffective or not tolerated.

Children exposed to valproate *in utero* are at a high risk of early neuro-developmental disorders (in 30–40% of cases) and congenital malformations (in approximately 10% of cases).

IMPORTANT ACTIONS FOR PHARMACISTS

Whenever you dispense valproate to any female patient:

- ✓ Detach the PATIENT CARD from the carton and give to the patient every time valproate is dispensed
- ✓ Ensure she has received the PATIENT GUIDE
- ✓ Remind her of the risks in pregnancy and the need for highly effective contraception and annual specialist review
- ✓ Advise to always use contraception and to see their doctor urgently should they be planning a pregnancy or become pregnant
- ✓ Advise her NOT TO STOP valproate medication and to immediately contact her GP or specialist in case of suspected pregnancy
- ✓ Dispense valproate in the original package. In situations where repackaging cannot be avoided ALWAYS provide a copy of the package leaflet and ALWAYS add this sticker with the warning to the outer box

Please ensure you cascade this important information to all dispensary staff.

Valproate
(Epilim, Depakote, Convulex, Episenta, Epival, Kentlim, Orlept, Sodium Valproate, Syonell, Valpal, Belvo & Dyzantil)

prevent
valproate pregnancy prevention programme

Guide: What women and d to know about valproate
(or your parent/caregiver/responsible person) if you are a girl (of any age) using potential taking any medicine containing valproate.

Medicines & Healthcare products Regulatory Agency

The information in this Guide has been approved by the MHRA

WARNING FOR WOMEN AND GIRLS
This medicine can seriously harm an unborn baby. Always use effective contraception during your treatment. If you are thinking about becoming pregnant, or you become pregnant, talk to your doctor straight away. Do not stop taking this medicine unless your doctor tells you to.

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 that appear.

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.