

FOR DISPENSARY USE ONLY

prevent
valproate pregnancy
prevention programme

UPDATED
NOVEMBER 2019

Valproate ▼: Pregnancy Prevention Programme

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



**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 neurodevelopmental disorders (in 30–40% of cases), including autism spectrum disorders, and congenital malformations (in approximately 10% of cases).

IMPORTANT ACTIONS FOR PHARMACISTS

Whenever you dispense valproate to any female patient:

- ✓ Provide the **PATIENT CARD** every time valproate is dispensed
- ✓ 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, or become, pregnant
- ✓ Advise her **NOT TO STOP** valproate medication and to immediately contact her GP or specialist in case of suspected pregnancy
- ✓ Ensure she has received the **PATIENT GUIDE**
- ✓ Dispense valproate in the original package. In situations where repackaging cannot be avoided always provide a copy of the package leaflet and 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)

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Guide: What women and girls need to know about valproate

For your parent/caregiver/responsible person if you are a girl (of any age) or a woman of childbearing potential taking any medicine containing valproate.

It is part of prevent - the valproate pregnancy prevention programme, which aims to minimize the risk that could occur through the use of valproate during pregnancy.

Valproate 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 GP or specialist straight away.

Do not stop taking valproate unless your doctor tells you to.

Please keep this booklet. You may need to read it again.

More information can also be found online at www.medicines.org.uk by entering "valproate" in the search box and then clicking on "Risk Materials" next to any of the medicines that appear. You can also search online for "MHRA valproate".

This Guide was last updated November 2019

Medicines & Healthcare products
Regulatory Agency

The information in this Guide has been approved by the MHRA



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 Patient Card and Valproate poster) can be ordered from Sanofi Medical Information on

0845 372 7101 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

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