

Valproate ▼ (Epilim): Pregnancy Prevention Programme



WARNING FOR WOMEN
AND GIRLS

Valproate should not be used in female children and women of childbearing potential unless other treatments are ineffective or not tolerated. Valproate must be prescribed and dispensed according to the Valproate Pregnancy Prevention Programme.

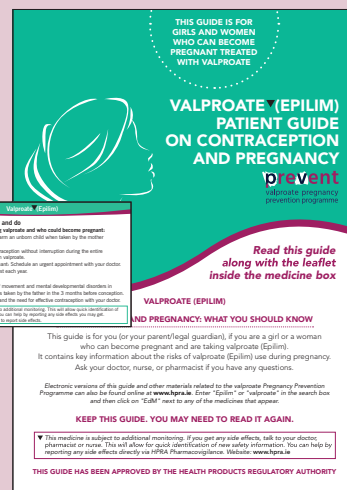
Children exposed in utero to valproate are at a high risk of serious neurodevelopmental disorders (in up to **30–40%** of cases) and major congenital malformations (in approximately **11%** of cases).

IMPORTANT ACTIONS FOR PHARMACISTS

Every time you dispense valproate to female children or women of childbearing potential:

- ✓ Provide a Valproate Patient Card every time you dispense a valproate preparation and ensure that the patient understands its content.
- ✓ Remind patients of the risks of birth defects/neurodevelopmental disorders from use of valproate in pregnancy and reinforce the need for effective contraception.
- ✓ If a woman of childbearing potential reports that she is not taking effective contraception, refer her to her GP.
- ✓ Dispense valproate in the original packaging with the outer carton warning text and symbol. Where repackaging cannot be avoided always provide a copy of the package leaflet and a patient card and add a warning sticker to the bag into which the blisters are placed.
- ✓ Ask if the patient has received a Valproate Patient Guide and provide a copy if necessary.
- ✓ Remind patients of the need for annual specialist review.

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



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

Copies of the Epilim pharmacy materials (Valproate warning sticker, Valproate Patient Guide, Valproate Patient Card and Valproate poster) can be ordered from Sanofi Medical Information on

01-4035600 or by emailing
IEmedinfo@sanofi.com

The Patient Guide and Card can also be downloaded from the HPRa website

www.hpra.ie

where it will be found linked with entries for medicines containing valproate.

CALL FOR REPORTING

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects your patients may get via HPRA Pharmacovigilance. Website: www.hpra.ie

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