Important Safety Information - Action Required - Read Now

Valproate medicines: only for use when no other treatment is effective or tolerated in girls, women of childbearing age, and women who are pregnant or planning pregnancy; important actions for pharmacists

This letter is for all pharmacists dispensing valproate-based medicines (sodium valproate [Epilim▼, Episenta▼]; valproic acid, sodium valproate [Epilim▼]; valproate semisodium [Depakote▼]).

Dear Healthcare Professional

This letter is sent in follow-up to the communication issued by the Medicines and Healthcare products Regulatory Agency in January 2015, and a further mailing on behalf of all valproate manufacturers in February 2016. It supplements the Patient Safety Alert on valproate issued by the MHRA and NHS Improvement on 6 April 2017 and those subsequently sent in Scotland, Wales and Northern Ireland.

Previous communications advised that **valproate should only be used in girls, women of childbearing age, and those who are pregnant or planning pregnancy when no other treatment is effective or tolerated.** This is because **children exposed in utero to valproate are at a high risk of serious developmental disorders (in up to 30–40% of cases) and congenital malformations (in approximately 10% of cases).**

Despite these communications, valproate continues to be used frequently in this patient group. A recent survey of women of childbearing age taking valproate for epilepsy has identified that 20% had not been informed of these risks and 80% had not received any written information. Prescribing data show little change in the rate of prescription of valproate to girls and women of childbearing age since 2015, regardless of the indication. **A significant number of patients remain at risk of inadvertent exposure to valproate in pregnancy and further efforts and actions are needed from prescribers and dispensers of valproate to reduce the risks that this entails**.

Please turn over to see the actions that you are being asked to perform.

THE RISK: Children exposed in utero to valproate are at a high risk of serious developmental disorders (in up to 30–40% of cases) and congenital malformations (in approximately 10% of cases).

For this reason, you are asked to take the following important actions:

1. **When dispensing any valproate preparation to female children, female adolescents, women of childbearing potential, or pregnant women CHECK that their prescriber has discussed the risks of in utero exposure with them and they are aware of these.**

2. **If the prescriber HAS NOT DISCUSSED the risk with the patient, CONTACT THE PRESCRIBER and REMIND them of their responsibility to do so and ask for an urgent follow-up action with patient.**

3. **PROVIDE a Valproate Patient Card every time you dispense a valproate preparation to female children, female adolescents, and women of childbearing potential or pregnant woman.**

4. **ASK if they have received a Valproate Patient Guide (booklet), and provide a copy if they have not received this or no longer have it in their possession.**

To support effective practice, the enclosed booklet "Important Information for Healthcare Professionals on the Risks of Valproate in Female Patients" provides information on the risks and actions prescribers are required to take. This is provided for your information.

Five Valproate Patient Cards are enclosed for you to provide to patients. These highlight the risks of taking valproate while pregnant and remind patients to always use contraception and to see their prescriber urgently should they be planning to or become pregnant.

Five copies of the "Valproate Patient Guide" are included for you to provide for those girls or women of childbearing potential who have not received a copy from their prescriber or no longer have it in their possession.

Further supplies of the Valproate Patient Card and Valproate Patient Guide will be supplied in a follow up delivery in 6 weeks. Additional copies can also be ordered, at no cost, by contacting Sanofi Medical Information on 0845 372 7101 or by emailing uk-medicalinformation@sanofi.com
The patient guide can also be downloaded from the EMC website (www.medicines.org.uk) where it will be found linked with entries for medicines containing valproate.

Finally, to help remind your dispensing staff to provide patients with the card and booklet, a shelf edge label for you to display with valproate packs and an information poster for pharmacists and dispensing staff have also been developed to display in your pharmacy. This will help support the objective of ensuring that every girl or women of childbearing age taking valproate is fully informed of the risks to an unborn child and has had the opportunity to discuss these with their prescriber.

A copy of the information poster and shelf edge label are included with this letter, and additional copies can be ordered from Sanofi's Medical Information department (as above), or downloaded from the EMC website (www.medicines.org.uk) where it will be found linked with entries for medicines containing valproate.

You may find it helpful to keep this letter, and refer especially to page 2 when dispensing valproate to girls and women of childbearing age. It may be helpful to display these two pages as a ready reference.

Call for reporting:
All valproate-containing drugs are subject to additional monitoring. Any suspected adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to the pharmaceutical company proving the valproate preparation, contactable at the address indicated on the packaging, in the Summary of Product Characteristics or Patient Leaflet, or in the BNF

Thank you for your co-operation in following these requirements. This will help ensure appropriate use of valproate in this patient group and minimise these significant risks.

Yours faithfully

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This letter is sent at the request and with the approval of the Medicines and Healthcare products Regulatory Agency.