

Valproate (Epilim▼, Depakote▼):
PREGNANCY PREVENTION PROGRAMME



This letter is for **specialists and specialist nurses** managing patients treated with valproate medicines and **general practitioners and other Healthcare Professionals** who provide care to these patients

Valproate medicines are sodium valproate [Epilim▼, Convulex▼, Episenta▼, Epival▼, Kentlim▼, Orlept▼, Valpal▼]; sodium valproate, valproic acid [Epilim Chrono/Chronosphere▼]; valproate semisodium [Depakote▼, Belvo▼ Syonell▼,]

January 2020

Dear Healthcare professional,

Please find enclosed the Valproate educational materials, part of the **“prevent” valproate Pregnancy Prevention Programme**. These materials provide information on the risks of valproate and the conditions for use. This is a routine redistribution and changes made to the materials are only to clarify the existing regulatory situation and not due to new advice. A summary of the changes made to the current materials has been provided in appendix 1 of this letter.

Enclosed please find:

- 1 copy of an **updated version** of the *Guide for Healthcare Professionals* including prescribers, pharmacists, and other healthcare providers involved in the care of girls and women of childbearing potential using valproate medicines. **This contains full detail of the valproate pregnancy prevention programme (“prevent”).**
- 1 copy of the **updated version** of the *Valproate Annual Risk Acknowledgement Form* for the prescriber to document that the patient has understood the risks in every annual visit. **This should be signed by the patient, then scanned and saved in her Patient Medical Record. A copy should be given to the patient and one copy sent to her GP.**
- 3 copies of the *Patient Guide* for the prescriber to **provide a copy to ALL girls and women of childbearing potential** who start treatment on valproate or who are continuing treatment with valproate. Note the advice in this Guide has not changed since the previous version so the patient does not need to replace her current version if she still has it.

A Patient Card is also available via the pharmacist to provide to all female patients when dispensing the product.

Additional hard copies of these materials can be ordered, by contacting Sanofi Medical Information on 0845 372 7101 or by emailing uk-medicalinformation@sanofi.com

The materials can also be downloaded from the eMC website (www.medicines.org.uk) linked with entries for medicines containing valproate.

For consistency all materials have been reprinted with a November 2019 date.

As a reminder:

- **Valproate should not be used in girls and women of childbearing potential** unless other treatments are ineffective or not tolerated, as judged by an experienced specialist.
- Children exposed to valproate in utero are at high risk of serious developmental disorders (in 30–40% of cases) and of congenital malformations (in approximately 10% of cases).
- **Important contraindications apply:**
 - In epilepsy:
 - valproate is contraindicated in girls and women of childbearing potential, unless the conditions of **the valproate pregnancy prevention programme (“prevent”)**, described in the documents enclosed, are met.
 - valproate is contraindicated in pregnancy unless there is no suitable alternative treatment.
 - In bipolar disorder:
 - valproate is contraindicated in girls and women of childbearing potential, unless the conditions of **the valproate pregnancy prevention programme (“prevent”)**, described in the documents enclosed, are met.
 - valproate is contraindicated in pregnancy.
- In girls and women of childbearing potential currently using valproate, management will need to be re-evaluated to ensure that the conditions of **the valproate pregnancy prevention programme (“prevent”)**, described in the documents enclosed, are met.

Call for reporting

All valproate medicines are subject to additional monitoring. This will allow quick identification of new safety information.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to the pharmaceutical company providing the valproate preparation.

Yours faithfully

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This letter is sent with the approval of the Medicines and Healthcare products Regulatory Agency (MHRA) and on behalf of all Marketing Authorisation Holders of Valproate containing products in the UK.

Appendix-1

What's new in the Guide for Healthcare Professionals:

The main changes made from the previous version (dated May 2018) are as follows:

- New section: Definition of specialists Prescribers (page 6)
- New section: "Contraception" (page 7)
- New section: "Does prevent apply to my patient? (page 8)
- Clarification that the provisions of prevent apply when a patient is being switched from valproate to another treatment (page 12)

These changes are to clarify the existing regulatory situation and not due to new advice.

What's new in the Annual Risk Assessment Form?

The Annual Risk Assessment form (ARAF) was updated in March 2019 to improve the layout and to clarify when a patient was exempt from the Pregnancy Prevention Plan. The only change since then is to update the date to November 2019 to bring in line with the other educational materials.