Valproate (Epilim▼, Depakote▼): IMPORTANT ACTIONS FOR PHARMACISTS

prevent
valproate pregnancy prevention programme

This letter is for all pharmacists dispensing valproate medicines

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 pharmacist,

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 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 pack of 20 *Patient Cards:* provide a card to all female patients when dispensing valproate to them. Note: If there is a Patient Card already attached to the box, please detach that copy and give to the patient. Do not stick the dispensing label on top of this card or over the warning on the front of the pack.

- 3 copies of the *Patient Guide:* provide to all female patients who do not have a copy. 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.

- 1 sheet of 14x Warning Stickers: for use if valproate is dispensed out of its original packaging

- 1 A4 poster: for display in the dispensary area to remind pharmacy staff of these requirements.

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:

- 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)

- Valproate medicines 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
- In girls and women of childbearing potential **contraindications** apply unless the conditions of **the valproate pregnancy prevention programme, called 'prevent'** are met.

PHARMACISTS are asked to take the following IMPORTANT ACTIONS:

- PROVIDE a Valproate Patient Card every time you dispense a valproate medicine to ALL female patients. Please also note that the outer boxes of valproate are being changed in order to include a removable patient card, to be detached and given to the female patient at the time of dispensation.
- When dispensing any valproate preparation to female children, adolescents, women of childbearing potential, or pregnant women CHECK that their prescriber has discussed the risks of exposure in pregnancy with them and they are aware of these and subsequently they are taking EFFECTIVE CONTRACEPTION unless already pregnant.
- If the prescriber HAS NOT DISCUSSED the risks with the patient or the patient is not taking effective contraception, tell them to CONTACT their GP or specialist for an urgent follow-up appointment.
- Advise the patients NOT TO STOP valproate medication and to immediately contact their GP or specialist in case of suspected pregnancy.
- Ask if they have received the Valproate Patient Guide and provide a copy if they have not received this or no longer have it in their possession.
- Dispense valproate in the ORIGINAL PACKAGE with the outer warning and avoid repacking. In the situations where this cannot be avoided, always provide a copy of the package leaflet, patient card, and add a warning sticker to the outer box.
- Please share this important information with all Pharmacy staff**.**

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

Dr Nabeel Shafaat
Medical Head Established Brands
Primary Care Business Unit, Sanofi UK

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.