PLEASE READ
Important Patient Safety Information
Approved by HPRA

Valproate (Epilim▼):
PREGNANCY PREVENTION PROGRAMME
Annual redistribution of educational materials

prevent
valproate pregnancy
prevention programme

February 2020

Dear Healthcare professional,

Please find enclosed Valproate educational materials **to prevent valproate (Epilim) exposure during pregnancy.** These materials provide information on the risks of valproate and the conditions for use and are being sent to you as part of the annual redistribution of educational materials for Epilim. The content of the educational materials remains unchanged since the last distribution of valproate educational materials.

Enclosed please find:

- 1 healthcare professional guide - which includes the actions for healthcare professionals.
- 5 patient guides - to be provided to all female patients when prescribing valproate (Epilim)
- 5 patient cards – to be provided by pharmacists to all female patients when dispensing valproate (Epilim) to them. Please also be informed 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 dispensing.
- 5 annual risk acknowledgment forms - to be used by the specialists at time of treatment initiation and during each annual review of valproate treatment by the specialist. The specialist should document that the patient has understood the risks at every annual visit. This should be signed by the patient and specialist and recorded in her patient medical record.

Electronic versions of these materials are also available on www.hpra.ie (enter 'Epilim' or 'valproate' in the 'Find a medicine' search box and click on 'EdM' next to any of the medicines that appear).

Call for reporting

Valproate (Epilim) is subject to additional monitoring.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie

sanofi-aventis Ireland Limited T/A SANOFI, Citywest Business Campus, Dublin 24, Ireland - Tel: +353 1. 40.35.600 - Fax: +353 1.40.35.601
Registered in Dublin, Ireland No. 166500 Directors: M. Dempsey, FX Duhalde (French)

Adverse events arising from the use of medicines manufactured by Sanofi may also be reported to the **Sanofi IE Pharmacovigilance** department at: Sanofi, 18 Riverwalk, Citywest Business Campus, Dublin 24.
Tel: +353 1 403 5600, Fax: +353 1 403 5687, Email: IEPharmacovigilance@sanofi.com

Should additional hardcopy versions of any of the materials be required, these can be ordered by contacting Sanofi Medical Information on Tel: (01) 403 5600 or e-mail: IEMedinfo@sanofi.com

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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Dr. Nabeel Shafaat
Established Products Medical Lead
Sanofi UK & Ireland