PLEASE READ
Important Patient Safety Information
Approved by HPRA

Valproate (Epilim▼): NEW restrictions on use
PREGNANCY PREVENTION PROGRAMME

prevent
valproate pregnancy
prevention programme

XX-XXX 2018

Dear Pharmacist,

This letter is sent in agreement with the Health Products Regulatory Authority (HPRA) to inform you of revised valproate (Epilim) educational materials **to prevent valproate exposure during pregnancy.**

Further to the communication of 16 April 2018 informing you of important **new contraindications, strengthened warnings and measures to prevent valproate exposure during pregnancy**, revised Educational Materials have been produced which provide information on the risks of valproate and the conditions for use. These include:

- a patient card (the packaging will be updated to include this on the outer carton) – to be provided by pharmacists to all female patients when dispensing valproate (Epilim) to them
- a patient guide - to be provided to all female patients when prescribing valproate (Epilim)
- a healthcare professional guide - which includes the actions for healthcare professionals
- an annual risk acknowledgment form - to be used by the specialists at time of treatment initiation and during each annual review of valproate treatment by the specialist. The prescriber should document that the patient has understood the risks at every annual visit. This should be signed by the patient and prescriber and recorded in her patient medical record.

Hardcopies of the patient guide, the patient card, the healthcare professional guide and the acknowledgement of risk form are enclosed. A patient card should be provided by pharmacists to all female patients when dispensing valproate (Epilim) to them. Electronic versions of materials are also available on www.hpra.ie (enter 'Epilim' or 'valproate' in the search box and click on 'EdM' next to any of the medicines that appear) and www.sanofi.ie.

Additionally, specific pharmacy materials are also enclosed:

- pharmacy poster
- pharmacy shelf barker
- warning stickers with pictogram

You are asked to display the poster and the shelf barker in the dispensary as a visual reminder to pharmacy staff of the pregnancy prevention programme and the warnings related to the use of valproate and the need to counsel female patients on the risks. When it is not possible to dispense valproate (Epilim) in the original packaging, add a warning sticker to the bag or box into which the blisters have been placed and always provide a copy of the package leaflet and patient card.

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PHARMACISTS are asked to take the following IMPORTANT ACTIONS when dispensing valproate (Epilim) to female patients:

- **Provide the 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 highly effective contraception, refer her to her GP**
- **Dispense valproate in the original package with the outer 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 and display the valproate poster and shelf barker in your dispensary as a visible reminder to staff of the pregnancy prevention programme, the warnings related to the use of valproate and the need to counsel female patients on the risks.**

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.

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

Siobhán Mitchell

Dr Siobhan Mitchell
Medical Director, Sanofi Ireland