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 Healthcare professional,

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

Key elements of the PREGNANCY PREVENTION PROGRAMME:

The prescriber must ensure that:

- the potential for pregnancy is assessed for all female patients.
- individual circumstances are evaluated in each case, involving the patient in the discussion, to guarantee her engagement, discuss therapeutic options and ensure her understanding of the risks and the measures needed to minimise the risks.
- the patient has **understood and acknowledged the risks** of congenital malformations and neurodevelopmental disorders, including the magnitude of these risks for children exposed to valproate in utero.

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- the patient understands the need to undergo **pregnancy testing prior to initiation of treatment** and during treatment, as needed.
- the patient is counselled regarding contraception, and that the patient is capable of complying with the **need to use effective contraception**, without interruption during the entire duration of treatment with valproate.
- the patient understands **the need for regular (at least annual) review of treatment by a specialist** experienced in the management of epilepsy or bipolar disorders.
- the patient **understands the need to consult her physician as soon as she is planning a pregnancy** before contraception is discontinued, to ensure enough time for switching to an alternative treatment prior to conception.
- the patient understands **the need to urgently consult her physician in case of pregnancy**.
- the patient has **received and understood the patient guide.**
- the patient has acknowledged that she has understood the hazards and necessary precautions associated with valproate use and has signed the **Annual Risk Acknowledgement Form** that should be recorded in her Patient Medical Records.

These conditions also concern women who are not sexually active unless the prescriber considers that there are compelling reasons to indicate that there is no risk of pregnancy.

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