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IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Valproate (Epilim▼):

Annual redistribution of educational materials: Updated Annual Risk Acknowledgement Form enclosed

prevent
valproate pregnancy prevention programme

June 2025

Dear Healthcare professional,

Please find enclosed valproate (Epilim) educational materials. These materials are being sent to you as part of the annual redistribution of educational materials for valproate.

Updates since last distribution:

The **Annual Risk Acknowledgement Form** has been updated following significant engagement between the HPRA and relevant stakeholders in the clinical and patient community. The key content remains the same however the updates aim to simplify the ARAF by removing duplication and also place greater focus on a shared patient and specialist approach by allowing for joint use of the form by patient and specialist together.

The key differences in the ARAF are:

- Part A has been reformatted so that it is part of the pack but is not within the ARAF itself.
- Current parts B and C are combined and replaced by a joint patient and specialist section.

The content of the remaining valproate educational materials remains unchanged since last distribution.

For girls and women of childbearing potential, healthcare professionals are reminded that:

- **Valproate must be initiated and supervised by a specialist experienced in the management of epilepsy or bipolar disorder. A specialist is defined as a consultant psychiatrist or a consultant neurologist who regularly manages bipolar disorder or complex epilepsy.**

- **Valproate should not be used in female children, girls and women of childbearing potential unless other treatments are ineffective or not tolerated.**
- **Valproate is highly teratogenic. Children exposed to valproate in utero are at high risk of neurodevelopmental disorders (NDDs) (in up to 30-40% of cases) and of major congenital malformations (in approximately 11% of cases).**
- **In bipolar disorder, valproate is contraindicated in pregnancy.**
- **In epilepsy, valproate is contraindicated in pregnancy unless there is no suitable alternative treatment.**
- **In any indication, valproate is contraindicated in women of childbearing potential, unless all the conditions of the pregnancy prevention programme 'prevent' are met.**
- **Conditions include assessment of potential for pregnancy, pregnancy testing, use of effective contraception, review of treatment at least annually and when planning a pregnancy or if pregnancy occurs. Female patients of childbearing potential should be counselled to ensure that they understand and acknowledge the risks of congenital malformations and neurodevelopmental disorders including the magnitude of these risks for children exposed to valproate in utero.**
- **These measures are described in the product information for Epilim and in the enclosed educational materials.**

For male patients, healthcare professionals are reminded that:

- **It is recommended that in male patients' valproate is initiated and supervised by a specialist experienced in treatment of epilepsy or bipolar disorder.**
- **Prescribers should inform male patients about the potential risk and discuss with them the need to consider effective contraception, including for a female partner, while using valproate and for 3 months after stopping the treatment.**
- **Treatment with valproate in male patients should be regularly reviewed by prescribers to evaluate whether valproate remains the most suitable treatment for the patient.**
- **For male patients planning to conceive a child, suitable alternative treatment options should be considered and discussed with the patient. Individual circumstances should be evaluated for each patient. It is recommended that advice from a specialist experienced in the management of epilepsy or bipolar disorder should be sought as appropriate.**
- **Male patients should be advised to not donate sperm during treatment and for at least 3 months after treatment discontinuation.**
- **The male patient guide should be provided to male patients**

Please refer to the Epilim HCP Guide and the Summary of Product Characteristics for further information on the role of specialists, GPs and pharmacists when treating males, girls and women of childbearing potential on valproate.

Enclosed please find for use in your clinical practice:

- 1 HCP guide – includes a dedicated section on the use of valproate in male patients and guidance on the actions for healthcare professionals on implementing the pregnancy prevention programme for girls and women of childbearing potential.
- 5 Male patient guides – to be provided to all male patients prescribed valproate. This should be used when discussing the risks of exposure to valproate in male patients and the need to consider effective contraception, including for a female partner, while using valproate and for at least 3 months after stopping the treatment.
- 5 Female patient guides - this should be used when discussing the risks of exposure to valproate during pregnancy and be provided to all female patients being prescribed valproate who have the potential to become pregnant.
- 5 **updated** Annual Risk Acknowledgment Forms - to be discussed and completed by the specialist with all female patients of childbearing potential treated with valproate – at treatment initiation (or when menarche is reached), at each annual visit, when a pregnancy is planned or if a pregnancy occurs. An interactive version of this form, which can be completed online and printed for final signature is available on the HPRA website detailed below.
- 5 patient cards - pharmacists should ensure a patient card is provided to all female patients of childbearing potential and male patients each time valproate is dispensed. The packaging for Epilim products includes the card on the outer carton.

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). Additional hardcopy versions of the materials can be ordered at any time by contacting Sanofi Medical Information on Tel: (01) 403 5600 or e-mail: IEMedinfo@sanofi.com

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. Website: www.hpra.ie

Adverse events should also be reported to Sanofi Ireland Ltd. Tel: 01 403 5600. Alternatively, send via email to IEPharmacovigilance@sanofi.com.

Yours faithfully

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