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IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE HPRA

An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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

prevent
valproate pregnancy prevention programme

April 2023

Dear Healthcare professional,

Please find enclosed valproate educational materials **to prevent the risk of valproate (Epilim) exposure during pregnancy and support the implementation of the Pregnancy Prevention Programme for Epilim.** The content of the educational materials remains unchanged since the last distribution of valproate educational materials.

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.**
- **Children exposed to valproate in utero are at high risk of neurodevelopmental disorders (in up to 30-40% of cases) and of major congenital malformations (in approximately 11% of cases).**
- **Valproate is contraindicated in women of childbearing potential, unless all the conditions of the pregnancy prevention programme 'prevent' are met. These are described in the product information for Epilim and in the enclosed educational materials.**
- **In epilepsy, valproate is contraindicated in pregnancy unless there is no suitable alternative treatment.**
- **In bipolar disorder, valproate is contraindicated in pregnancy.**

General Practitioners who renew prescriptions for valproate to girls and women of childbearing potential are reminded to:

- Ensure women of childbearing potential are on *prevent* – the Pregnancy Prevention Programme for Epilim.
- Any woman of childbearing potential who has not been seen by her specialist should be referred for a review of her treatment to ensure that she and the specialist have considered treatment options and discussed the teratogenic risks of valproate and the need to be on *prevent*.
- Ensure women of childbearing potential are referred to their specialist at least annually for a review of treatment.
- Ensure that your patient has an up-to-date Annual Risk Acknowledgement Form (completed with her specialist at the annual review) on file when you renew a prescription.
- Ensure that your patient understands the risks of congenital malformations and neurodevelopmental disorders for children exposed to valproate *in utero* – provide them with a copy of the Patient Guide, if necessary.
- Ensure continuous use of highly effective contraception in all women of childbearing potential – consider pregnancy testing if needed at any time during valproate treatment.
- Refer your patient to the specialist urgently in case of an unplanned pregnancy or where the patient wants to plan a pregnancy.

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

The enclosed materials provide information on the nature and magnitude of the teratogenic risks of valproate and the actions necessary at clinical level to minimise the risk of exposure to valproate during pregnancy. The materials should be used to ensure your patient understands the risks to children exposed to valproate in-utero and the need to use effective contraception during treatment with valproate.

These materials are being sent to you as part of the annual redistribution of educational materials for Epilim.

Enclosed please find for use in your clinical practice:

- 1 healthcare professional guide – includes guidance on the actions for healthcare professionals on implementing the pregnancy prevention programme.
- 5 patient guides - this should be used when discussing the risks of exposure to valproate (Epilim) during pregnancy and be provided to all female patients being prescribed valproate who have the potential to become pregnant.
- 5 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.
- 2 patient cards - pharmacists should ensure a card is provided to all female patients of childbearing potential each time valproate (Epilim) is dispensed. The packaging for Epilim products now 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.

Thank you for your co-operation in fulfilling these requirements. This will help ensure appropriate use of valproate in this patient group and minimise these significant risks.

Yours faithfully

R Grundy

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