PLEASE READ
Important Patient Safety Information
Approved by HPRA

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

prevent
valproate pregnancy
prevention programme

February 2022

Dear Healthcare professional,

Please find enclosed updated valproate educational materials **to prevent the risk of valproate (Epilim) exposure during pregnancy and support the implementation of the Pregnancy Prevention Programme for Epilim.**

- **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 serious developmental disorders (in up to 30-40% of cases) and of 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**

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.

Updates since last annual distribution:

- The **Healthcare Professional Guide, Patient Guide and Annual Risk Acknowledgement Form** were updated in February 2022 following changes in the prescribing information approved by the Health Products Regulatory Authority. These updates include information on the risks of major congenital malformations and neurodevelopmental disorders in children after in utero exposure to antiepileptic polytherapy including valproate and the risk of eye malformations after in utero exposure to valproate. We are now providing you with hardcopies of these updated materials within this annual distribution.

Enclosed please find for use in your clinical practice:

- 1 **updated** healthcare professional guide – includes guidance on the actions for healthcare professionals on implementing the pregnancy prevention programme.
- 5 **updated** 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 **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.
- 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

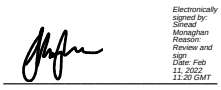
Valproate (Epilim▼) is subject to additional monitoring.

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 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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