PLEASE READ
Important Patient Safety Information
Approved by HPRA

Valproate (Epilim▼):
PREGNANCY PREVENTION PROGRAMME
Annual redistribution of educational materials: Updated materials enclosed including reformatted Annual Risk Acknowledgement Form

prevent
valproate pregnancy
prevention programme

February 2021

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 10% 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.

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Updates since last annual distribution:

- The **Healthcare Professional and Patient Guides** were updated in July 2020 to include new information on the risk of hearing impairment or deafness and updated information on the magnitude of the risk of ADHD, in children exposed to valproate in utero. You will have previously received a letter detailing these changes and availability of the updated guides on the HPRA website. We are now providing you with hardcopies of the updated guides within this annual distribution.
- The **Annual Risk Acknowledgement Form** has been updated to provide clearer guidance to specialists on the completion of the form and to make it more user-friendly. The updated form is also now available in a new interactive digital format, so it can be completed online before being printed and signed by the specialist and patient.

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, 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 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

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

Dr. Arunesh Sil
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