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 Pharmacist,

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** and **Patient Guide** 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.

  Additional specific pharmacy materials including the pharmacy poster and shelf barker have also been updated as result of this change and we are now providing you with hardcopies of all updated materials within this annual distribution.

Enclosed please find for use in your practice:

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

- 5 **updated** patient guides - to be provided to all female patients when valproate (Epilim) is prescribed

- 1 pack (25) patient cards –pharmacists should provide a patient card to all female patients of childbearing potential with every valproate (Epilim) dispensing and ensure that the patient understands its content, including the need for effective contraception. The patient card is now included as part of the Epilim carton. The patient card is perforated and should be detached from the outer carton and given to the female patientat the time of each dispensing.

For information, an Annual Risk Acknowledgement Form also forms part of the pregnancy prevention programme for valproate (Epilim) for use by specialist prescribers and their patients. This form was also recently updated and is available on the HPRA website or on request from Sanofi Medical Information (details below).

Additionally, **specific pharmacy materials** are enclosed:

- 1 **updated** pharmacy poster

- 2 **updated** pharmacy shelf barkers

Please display the poster and the shelf barker in the dispensary as a visual reminder to pharmacy staff of the pregnancy prevention programme, the warnings related to the use of valproate and the need to counsel female patients on the risks.

- 2 sheets of Valproate warning stickers with pictogram (14 per sheet)

When it is not possible to dispense valproate (Epilim) in the original packaging, add a warning sticker to the bag or box into which the blisters have been placed and always provide a copy of the package leaflet and patient card.

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

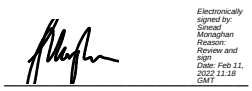
Valproate (Epilim▼) is subject to additional monitoring.

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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