

PLEASE READ

**IMPORTANT MEDICINE
SAFETY INFORMATION**

APPROVED
BY THE



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



April 2023

Dear Pharmacist,

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.**

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 practice:

- 1 healthcare professional guide – includes guidance on the actions for healthcare professionals on implementing the pregnancy prevention programme.
- 5 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 patient at 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 is available on the HPRA website or on request from Sanofi Medical Information (details below).

Additionally, specific pharmacy materials are enclosed:

- 1 pharmacy poster
- 2 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: IMedinfo@sanofi.com

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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 HPRC 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

A handwritten signature in black ink that reads "R Grundy".

Rod Grundy
Senior Medical Advisor
Sanofi UK & Ireland