Valproate-containing medicines: updates to educational materials

This letter contains important information on how to access the risk minimisation materials for Valproate-containing medicines- sodium valproate [Epilim▼, Convulex▼, Episenta▼, Epival▼]; sodium valproate, valproic acid [Epilim Chrono/Chronosphere▼, Dyzantil▼]; valproate semisodium [Depakote▼, Syonell▼, Belvo▼]

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Dear Healthcare Professional,

Please find below the live links to the educational materials for valproate containing medicines approved by the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK.

Please note that following updates have been made to educational materials since last distribution in January 2024:

- **New measures regarding the potential risk of neurodevelopmental disorders in children of fathers treated with valproate in the 3 months prior to conception**
- **The risk of lower weight at birth for the gestational age in children exposed to valproate during pregnancy**

The existing patient guide has been split and the following new materials have been created:

- Male Patient Guide
- Female Patient Guide

In addition, the following existing materials have been updated:

- HCP Guide
- Patient Card

Additional hard copies of these materials
can be ordered by contacting Sanofi Medical Information on 0800 035 2525 or by emailing uk-medicalinformation@sanofi.com.

Electronic copies are also available from the eMC website (http://www.medicines.org.uk/emc/) linked with entries for valproate-containing medicines.

Or alternatively via scanning the following QR code:

Patient materials (e.g., Patient Information Leaflet, Female Patient Guide, Male Patient Guide, Patient Card, Annual Risk Acknowledgement Form for Female Patients, Risk Acknowledgement Form for males starting valproate) can also be found by scanning the QR Code printed on the Patient Information Leaflet. **Please highlight this QR code to your patients.**

Valproate is indicated to treat epilepsy and bipolar disorder.

Adverse Event Reporting:

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information.

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme (https://yellowcard.mhra.gov.uk/).

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle.

You can report via:

- the Yellow Card website (https://yellowcard.mhra.gov.uk)
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

- Valproate▼ is subject to additional monitoring. This will allow quick identification of new safety information.
- Please report ANY suspected adverse drug reactions (ADRs) to new drugs and vaccines identified by the black triangles▼ to the MHRA through the Yellow Card Scheme.

Yours faithfully,



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Country Medical Director/Medical Head UKIE Speciality Care