Date: December 2024

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Epilim Chrono 500 Controlled Release Tablets (sodium valproate) – pack size 30 tablets:
Partial product name error on the blister foil

Dear Healthcare Professional,

Summary:

To ensure continuity in supply, SANOFI has obtained an exemption made under Regulation 266 of the Human Medicines Regulations (2012) and Article 63.3 of Directive 2001/83/EC from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply packs of Epilim Chrono 500 Controlled Release Tablets (batch number 4R2P2 -28,168 units, 4R2P3 – 28,280 units, 4R2P4 – 28,579 units, 4R2P5 – 27,688 units, 4R2P6 – 27,925 units and 4R2P7 – 9,983 units), which are expected to be on the UK market from 1st April 2025 to 31st May 2025.

Please note the following:

- This product is considered licensed in the UK.
- There is a partial product name error on the blister foil of the aforementioned batches whereby both "Epilim Chrono 500" and "Epilim Chrono 50" has been printed on a single blister foil.
- When dispensing this product, please inform patients the blister foil in their pack has a partial product name error.
    - Please note, there is no Epilim Chrono 50 licenced in the UK.
    - Please see the Annex below demonstrating the error in the blister foil.
- The MHRA has agreed to an exemption granted in accordance with regulation 266(4)(a) of the Human Medicines Regulations (HMR) 2012 / Article 63.3 of Directive 2001/83/EC, from the obligation that certain particulars should appear on the outer and immediate packaging of Epilim Chrono 500 Controlled Release Tablets.
- Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to patients.

Call for reporting
Healthcare professionals are asked to report suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://yellowcard.mhra.gov.uk/, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects can also be reported by calling 0800 731 6789 for free.

Suspected adverse reactions should also be reported to Sanofi: Tel: 0800 0902314. Email: UK-drugsafety@sanofi.com

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

Company contact point
If you have any questions about this letter or require more information about Epilim Chrono 500 Controlled Tablets, please contact Sanofi Medical Information at 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK or telephone 0800 035 2525 or email uk-medicalinformation@sanofi.com

Yours faithfully,

Deborah Woods, MSc RN (Ret) CME
Head of Medical, General Medicines UK & Ireland
Country Medical Lead, UK and Ireland

Felicia Pinto
Head of Regulatory Affairs UK & Ireland

Annex 1 – Blister foil highlighting the partial name error on Epilim Chrono 500 Controlled Release Tablets