Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy and Wholesaler Level

Date: 14 October 2020 EL (20)A/48* Our Ref: MDR 159-08/20

Dear Healthcare Professional,

Sanofi

Epilim 500mg Gastro-Resistant Tablets PL 04425/0303

Batch Number	Expiry Date	Pack Size	First Distributed
R0601	08/2022	30	06 November 2019
R0602	08/2022	30	05 November 2019
R0603	08/2022	30	06 November 2019

Active Pharmaceutical Ingredient: sodium valproate

Brief description of the problem
Sanofi is recalling the above batches of product as a precautionary measure due to out of specification results for disintegration test during routine stability testing.

Advice for healthcare professionals
Stop supplying the above batches immediately. Quarantine all stock and return it to your supplier using your supplier's approved process.

Further Information
For stock control enquiries please contact GB-CustomerServices@sanofi.com
Phone number: 0800 854 430

For medical information enquiries please contact uk-medicalinformation@sanofi.com
Phone number: 0800 035 25 25

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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