Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action within 48 hours
Pharmacy/Wholesaler Level Recall

Date: 02 March 2020 EL (20)A/13 Our Ref: MDR 194-02/20

Dear Healthcare Professional,

AOP Orphan Pharmaceuticals AG

Tetrabenazine 25 mg tablets PL 21344/0015

Batch Number	Expiry Date	Pack Size	First Distributed
T1704UK	09/2020	112	31-Dec-2017

Brief description of the problem
AOP Orphan Pharmaceuticals AG is recalling all unexpired stock of the above batch of Tetrabenazine 25 mg tablets (from pharmacies and wholesalers) as a precautionary measure due to out of specification results for the assay, obtained during routine stability testing.

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

Further Information
For more information or medical information queries, please contact medinfo@aoporphan.com

For stock control queries, please contact orderservice@aoporphan.com

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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