



DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Patient, Pharmacy and Wholesaler Level

Date: 02 July 2020

EL (20)A/27

Our Ref: MDR 057-03/19

Dear Healthcare Professional,

BCM Specials Limited

Mepacrine Hydrochloride 100 mg tablets

Unlicensed Medicine
– MS 34777

Batch Number	Expiry Date	Pack Size	First Distributed
85641	January 2022	50 Tablets	Oct-2019

Active Pharmaceutical Ingredient: Mepacrine

Brief description of the problem

BCM Specials Limited has informed us that a number of foreign body particulates including glass and rubber have been found in one of the containers of the Active Pharmaceutical Ingredient (API) used in the manufacture of Mepacrine Hydrochloride 100mg tablets. A small amount of the affected API (comparative to the API present in batch 85641) has been used in the manufacture of batch 85641 Mepacrine Hydrochloride tablets.

No foreign body particulates were identified during the manufacturing process, routine associated batch analysis or investigative analysis performed to date, however, because of the use of API from the affected container in the manufacture of batch 85641 the decision to recall all available stock from this batch has been made as a precautionary measure.

Advice for healthcare professionals

- Contact patients who have been supplied Mepacrine Hydrochloride 100mg Tablets from the affected batch 85641 and ask them to stop using tablets from this batch as soon as possible and return any unused medicine to their pharmacy.
- Stop supplying the above products immediately and remove from the shelves within your store. Quarantine all remaining stock and return it to your supplier using your supplier's approved process

Further Information

For stock control queries please contact BCM Specials Limited., Telephone +44 (0)115 968 6075 or email specials.regulatory.bcm@fareva.com

For any medical information enquires please contact BCM Specials Limited., Telephone +44 (0)115 968 6075 or email specials.regulatory.bcm@fareva.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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