

DRUG ALERT

CLASS 3 MEDICINES RECALL

Action Within 5 Days

Pharmacy and Wholesaler Level

Dear Healthcare Professional

Advanz Pharma

Carbimazole 10mg Tablets

PL
20072/0244

Batch Number	Expiry Date	Pack Size	First Distributed
120963	September 2021	1 x100	20 May 2020
121025	September 2021	1 x100	19 January 2021

Carbimazole 15mg Tablets

PL
20072/0245

Batch Number	Expiry Date	Pack Size	First Distributed
120967	September 2021	1 x100	26 June 2020
121028	September 2021	1 x100	27 May 2020

Active Pharmaceutical Ingredient: carbimazole

Brief description of the problem

Advanz Pharma is recalling the above batches of carbimazole tablets as a precautionary measure, due to an out of specification observation for tablet appearance of samples during routine stability testing. Based on the investigation performed, the observed defect was related to oxidation of the excipient red iron oxide on the surface of the tablets, due to a lack of proper mixing during the manufacturing process. There is no safety or efficacy issues as a result of this observation.



Advice for healthcare professionals

Stop supplying the above batches 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 +44 (0) 8700 70 30 33 , or email medicalinformation@advanzpharma.com

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this notice.

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

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TO ALL CHEMISTS, DOCTORS ON THE LISTS

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21st May 2021

Pharmaceutical website: <http://www.hscbusiness.hscni.net>