



# MEDICINES RECALL

## CLASS 3 MEDICINES RECALL

Action Within 5 Days  
Pharmacy/Wholesaler Level Recall

Date: 20 May 2021

EL (21)A/13

Our Ref: MDR 359-04/21

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](mailto:medicalinformation@advanzpharma.com)

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



Medicines & Healthcare products  
Regulatory Agency



Yours faithfully

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