

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action within 48 Hours

Pharmacy and Wholesaler Level Recall

Dear Healthcare Professional

Ennogen Pharma Limited

Trimethoprim 200mg Tablets

PL 40147/0083

Batch Number	Expiry Date	Pack Size	First Distributed
1403288	30/09/2023	14 Tablets	21/01/2021

Active Pharmaceutical Ingredient: trimethoprim

Brief description of the problem

Ennogen Pharma Limited are recalling the above batch as a precautionary measure due to the investigation of market complaints. The Marketing Authorisation Holder has received two complaints related to an observation that the sealed container contained a foreign tablet, which following an investigation has been confirmed and identified as Trimethoprim 100mg Tablets (also manufactured by Ennogen Pharma Limited).

Extracts from Patient Information Leaflets:

What Trimethoprim Tablets look like and contents of the pack

- Trimethoprim Tablets 100mg are white, round, flat faced bevelled edge tablet with an approximate diameter of 7.5mm, embossed with 'T2' on one side and plain on the other side.
- Trimethoprim Tablets 200mg are white, round, biconvex tablets with an approximate diameter of 9.0mm, embossed with 'T & 3' separated by a score line on one side and plain on the other side. The score line is not intended for breaking the tablet.



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 Ennogen QA at qagenerics@ennogen.com.

For stock control queries, please contact Alex Durall and Claire Willey on alex@ennogen.com and claire@ennogen.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 dispensing General Medical Practitioners directly.

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TO ALL CHEMISTS, DOCTORS ON THE LISTS

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22nd April 2021

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