

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Distribute to Pharmacy, Retail and Wholesaler Level

Dear Healthcare Professional

Ennogen Pharma Limited

Trimogal 100mg Tablets (POM)

PL 40147/0082

Batch Number	Expiry Date	Pack Size	First Distributed
1402264	09/2021	28	03/02/2020
1402265	09/2021	28	03/02/2020
1402266	09/2021	28	09/03/2020

Trimogal 200mg Tablets (POM)

PL 40147/0083

Batch Number	Expiry Date	Pack Size	First Distributed
1402171	07/2021	148	02/03/2020
1402262	08/2021	148	02/03/2020
1402263	08/2021	148	12/03/2020

Active pharmaceutical ingredient: trimethoprim

Brief description of the problem

Ennogen Pharma Limited has informed us that the Patient Information Leaflets (PILs) within the packs for the above batches contain an error in Section 3 (How To Take Trimogal Tablets) with regard to the dosage instructions for children under 6 years.

Section 3 (How To Take Trimogal Tablets)

Incorrect information in the PILs of the affected batches	Correct information that should be in the PILs
<p>Children aged 6 months to 6 years* 500mg twice a day (see * below)</p> <p>*For children a lower strength tablet or a syrup may be more suitable, especially for smaller children.</p>	<p>Children under 6 years This tablet form of Trimogal is not recommended for use in children under 6 years.</p>

Advice for healthcare professionals

When dispensing this medicine from the affected batches listed above, please ensure that the correct PIL is issued.

The correct PILs are available from the electronic medicines compendium (EMC) website by clicking on the links below:

[PIL for Trimogal 100mg Tablets](#)

[PIL for Trimogal 200mg Tablets](#)

Alternatively the correct PILs are also available from the MHRA website by clicking [here](#).

Further Information

For more information or medical information queries, please contact:

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

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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20th July 2020

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