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#### **IMMEDIATE MESSAGE TO:**

- 1. Directors of Pharmacy
- 2. Medical Directors NHS Boards

20 July 2020

Dear Healthcare Professional,

# CLASS 4 DRUG ALERT – NO 31 2020 - MEDICINES DEFECT INFORMATION – CAUTION IN USE – ENNOGEN PHARMA LIMITED TRIMOGAL 100 AND 200MG TABLETS

Please see the attached drug alert for onward transmission as below.

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY Medicines Policy Team











## DRUG ALERT CLASS 4 MEDICINES DEFECT INFORMATION

## Caution in Use Distribute to Pharmacy, Retail and Wholesaler Level

Date: 20 July 2020 EL (20)A/031 Our Ref: MDR 134-07/20

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	
Children aged 6 months to 6 years*	Children under 6 years	
500mg twice a day (see * below)	This tablet form of Trimogal is not recommended for use in children under 6 years.	
*For children a lower strength tablet or a syrup may be more suitable, especially for smaller children.		

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### 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:

#### **Ennogen Pharma Ltd**

Units G2-G4 Riverside Industrial Estate Riverside Way Dartford Kent DA1 5BS

Email: Info@Ennogen.com

Tel: 01322 629 220 Fax: 01322 311 897

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

NHS England and NHS Improvement Regional Offices are asked to forward this alert to community pharmacy contractors.

Yours faithfully

Defective Medicines Report Centre 10 South Colonnade Canary Wharf London E14 4PU Telephone +44 (0)20 3080 6574

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