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Direct Healthcare Professional Communication

Trimogal 100mg Tablets
Ennogen Pharma Limited UK; PL 40147/0082 (AA565/40403)

Following a notification received from the Marketing Authorization Holder of Trimethoprim 100mg Tablets in the UK, Ennogen Pharma Limited, the Central procurement and Supplies Unit in agreement with the Malta Medicines Authority would like to inform you of the following safety information update:

Summary

- Trimogal is an anti-bacterial drug containing trimethoprim which is licensed and distributed locally within the Government Healthcare Services by the CPSU.
- The UK MAH has informed that two batches in circulation contain an error in Section 3 (How To Take Trimogal Tablets) with regard to the dosage instructions for children under 6 years.
- In view of this, the product information on the patient insert has been revised to show that the tablet form of Trimogal is not recommended for use in children under 6 years.

Background on the safety concern

Trimethoprim is a systemic antibiotic that inhibits the conversion of bacterial dihydrofolic acid to tetrahydrofolic acid, required for the synthesis of some amino acids. Trimogal is indicated in urinary tract and respiratory tract infections, particularly for the treatment of pneumonia and in patients sensitive to sulphonamides.

The Patient Information Leaflets (PILs) provided with Trimogal, which is currently licensed and distributed locally within the Government Healthcare Services contain an error in Section 3 (How To Take Trimogal Tablets) with regard to the dosage instructions for children under 6 years.

The affected packs include the batches listed below:

BATCH	EXPIRY	PACK SIZE
1402264	30/09/2021	28
1402266	30/09/2021	28

In view of this, the product information on the patient insert has been revised as shown in the attached insert to reflect the following changes:

Incorrect information in the patient information leaflet of the affected batches
Children aged 6 months to 6 years*
500mg twice a day (see * below)

*For children a lower strength tablet or a syrup may be more suitable, especially for smaller children

Correct information in the patient information leaflet of the affected batches
Children under 6 years
This tablet form of Trimogal is not recommended for use in children under 6 years.

Call for reporting
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are reminded to continue to report suspected adverse reactions in accordance with the national spontaneous reporting system. Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Post-licensing directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta or sent by email to postlicensing.medicinesauthority@gov.mt.