

Drug Alert

CLASS 3 MEDICINES RECALL

Action Within 5 Days

Date: 24th April 2017

Our Ref: MDR 6-04/2017

Dear Healthcare Professional,

Cherubino Ltd.

(Delf Building, Sliema Road, Gzira)

Zithroplus 500mg film-coated tablets, 3 tablets per pack
(Azithromycin)

AA729/17301

Batch Number	Expiry Date	Pack Size	First Distributed
661709	06/2019	3 tablets per pack	Malta

Under the supervision of the Medicines Authority, Malta Cherubino Ltd. (the Marketing Authorisation Holder: MAH) in collaboration with Balu S.A Greece (Product Licence Holder) is initialising a recall for Zithroplus 500mg film coated tablets (Azithromycin) for Lot no **661709**, Expiry Date 06/2019 (3 tablets per pack).

The batch on the outer packaging is 66709 while the batch number on the inner packaging is 661709. The actual batch number should be 661709 as per the inner packaging and as per the Certificate of Analysis.

This product defect does not pose any significant hazard to health and it is not related to quality of the inner medicine but is related only to packaging issues.

Wholesale dealers and pharmacies are asked to quarantine all stock of the above product with batch number **661709**.

Yours faithfully,

Judit FEHÉR
Medicines Inspector

Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000
info.medicinesauthority@gov.mt | (+356) 23 439 000
www.medicinesauthority.gov.mt