

Licensing Authority
Superintendent of Public Health

Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 17th May 2016

Our Ref: MDR 13-05/16

Dear Healthcare Professional,

EcosseLtd.

T/G Triq Valletta

Luqa LQA 6000-Malta

Augmentin Duo 400/57mg Oral Suspension-35ml

PI555/05601A

Amoxicillin Trihydrate/ Potassium Clavulanate

Batch Number	Expiry Date	Pack Size	First Distributed
727934	01/2017	35ml	11/04/2016

The reconstitution directions stated on the Augmentin Duo 400/57mg x 35ml pack is incorrect. This should read 'Add 32 ml of water (or add water in 2 portions up to the line on the bottle or label). Invert and shake well', instead of the 'Add 64ml of water....' as stated on the label.

Kindly quarantine the stock; this will be collected by Ecosse Ltd and followed up accordingly.

Yours faithfully

Clint Pace

Medicines Authority Distribution (if applicable):
Licensing Authority
Superintendent of Public Health