Medicines & Healthcare products Regulatory Agency

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy Level Recall

Date: 13-May-2019 EL (19) A/12 Our Ref: MDR 24-05/19

Dear Healthcare Professional,

Sandoz Ltd.

Co-amoxiclav 125 mg/31.25 mg/5 ml Powder for Oral Suspension;	**PL 04416/0514**
Co-amoxiclav 250 mg/62.5 mg/5 ml Powder for Oral Suspension	**PL 04416/0515**

(Co-amoxiclav: Amoxicillin trihydrate/Potassium Clavulanate)

Batch Number	Expiry Date	Pack Size	First Distributed
HT6202	Feb 2021	100 ml	Sep 2018
HT7923	Feb 2021	100 ml	Jul 2018

Sandoz Ltd. have been notified of a potential packaging problem relating to poor seal adherence which could cause clumping of the powder within the bottle. A poor bottle seal could lead to degradation of the clavulanic acid within the powder and could potentially render the product ineffective.

This recall is a precautionary measure. No complaints or adverse events relating to this defect have been received by the company from the UK market.

Wholesalers and health care professionals:
Stop supplying the above noted batches of this product
Remaining stocks of the impacted batches should be quarantined and returned to your original supplier

Company Contacts for further information:
For enquiries relating to stock returns please contact Sandoz Limited Customer Services on 01276 698607 or email sales.sandoz-gb@sandoz.com

For medical information enquiries, please contact Sandoz Medical Information Team on 01276 698101 or email sandozgb@EU.propharmagroup.com

We do not anticipate any shortages of this product on the market This precautionary recall is related to two batches only.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS Regional teams are asked to forward this to relevant clinics, general practitioners and community pharmacists.

Yours faithfully

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