



DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 11 November 2019

EL(19)A/34

Our Ref: MDR 037-10/19

Dear Healthcare Professional,

Sandoz Limited

Omeprazole 40 mg Powder for Solution for Infusion

PL 04416/0701

Batch Number	Expiry Date	Pack Size	First Distributed
JS1355	31 January 2021	5 vials per carton	21 May 2019

Brief description of the problem

Sandoz Limited is recalling the above batch due to the occurrence of degradation in some vials, resulting in green discoloration of the powder in the vial, leading to increased levels of impurities/degradation products in the medicine. The manufacturer has confirmed the root cause to be an extended exposure to a UV light located within the warehouse and this only affects the batch listed above.

Advice for healthcare professionals

- Please quarantine all remaining stock of the above batch and return it to your original supplier using your supplier's approved process.

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.

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, dispensing general practitioners and community pharmacists.

Yours faithfully

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