

# Public Health Link

from the Chief Medical Officer for Wales

<b>Distribution:</b>	As Appendix 2
<b>From:</b>	Chief Pharmaceutical Officer, Andrew Evans
<b>Date:</b>	11 November 2019
<b>Reference:</b>	CEM/CPhA/2019/34
<b>Category:</b>	Class 2: Action With 48 Hours
<b>Title:</b>	Class 2 Drug Alert, Action Within 48 Hours, Sandoz Limited, Omeprazole 40mg Powder For Solution For Infusion
<b>For Action by:</b>	<p>Dispensing General Practitioners – Ensure all working in your dispensary see this alert and a copy is held on your locum file.</p> <p>Community Pharmacies</p> <p>Hospital pharmacies – Action as below.</p> <p>Chief Pharmacists - Action as below.</p> <p>Medical Directors – Distribute to appropriate clinicians for action as below.</p>
<b>For Information:</b>	See Annex 2 – Distribution List
<b>What is this about:</b>	Full details are set out below.
<b>Why has it been sent:</b>	For your information, action and to pass on to colleagues.

## Issue:

Sandoz Limited is recalling Omeprazole 40mg Powder for Solution for Infusion batch JS1355 due to the occurrence of degradation in some vials, resulting in green discolouration of the powder in the vial, leading to increased levels of impurities/degradation products in the medicine.

Full details of the drug alert are included in the attached PDF file. Please forward to listed recipients. This information is also published on the MHRA website <https://www.gov.uk/drug-device-alerts>.

## Appendix 1

- To: Chief Executives of Health Boards and NHS Trusts
- To: Medical Directors of Health Boards
- To: Nurse Directors Health Boards
- To: Directors of Public Health
- To: Hospital Principals and Chief Pharmacists to action as per alert

**To: NHS Wales Shared Services Partnership to forward to:**

Dispensing General Practitioners – Ensure all working in your dispensary see this alert and a copy is held on your locum file.

Community Pharmacies

Deputising services

HB Prescribing Advisers

Independent/Private clinics and Hospitals and Hospices throughout Wales



# 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](mailto:sales.sandoz-gb@sandoz.com)

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