

Public Health Link

from the Chief Medical Officer for Wales

Distribution:	As Appendix 2
From:	Chief Pharmaceutical Officer, Andrew Evans
Date:	24 July 2019
Reference:	CEM/CPhA/2019/18
Category:	Class 2 - Action within 48 hours
Title:	Drug Alert Class 2, Action Within 48 Hours, Chanelle Medical, Bisacodyl 5mg Gastro-Resistant Tablets
For Action by:	<p>All General Practitioners</p> <p>Dispensing General Practitioners – please ensure this message is seen by all working in your dispensary and retain a copy in your 'locum information pack'</p> <p>Community Pharmacists</p> <p>Hospital pharmacies</p> <p>Chief Pharmacists</p>
For Information:	See Annex 2 – Distribution List
What is this about:	Full details are set out below.
Why has it been sent:	For your information, action and to pass on to colleagues.

Issue:

Chanelle Medical is recalling one batch of the above product because a small number of packs have been found to contain tablets which are stuck together, with mould observed on some tablets.

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:**

All General Practitioners

Dispensing General

Community Pharmacists

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 Level Recall

Date: 24 July 2019

EL (19)A/18

Our Ref: MDR 34-04/19

Dear Healthcare Professional,

Chanelle Medical

Bisacodyl 5mg Gastro-Resistant Tablets

PL 13931/0005

Batch Number	Expiry Date	Pack Size	First Distributed
25074A	01/2021	1 x 1000	19 May 2018

Brief description of problem

Chanelle Medical is recalling the above batch because a small number of packs have been found to contain tablets which are stuck together, with mould observed on some tablets. The mould has been identified as a *Penicillium* species. It is unlikely that affected tablets will have got to patient level as the sticking is noticeable on opening the pack.

Advice for Healthcare Professionals and Wholesalers

- Stop supplying the batches listed above immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.
- Although only batch 25074A is being recalled, we understand that several batches were manufactured as part of the same campaign. If tablets which are stuck together or show microbial growth are seen for any other batch please do not dispense them. Please notify Chanelle Medical and return to your supplier immediately.
- The correct storage of Bisacodyl 5mg Gastro-Resistant tablets is essential to ensure maintenance of the quality of the product. As indicated on the PIL 'Do not store above 25°C. Store in the original container. Keep container tightly closed'.

Company contacts for further information

For stock enquiries, please contact:

David Hammond, General Manager, Healthcare Pharma. Email: rp@healthcarepharma.co.uk

Tel: 01233 822 297

For medical information enquiries, please contact:

Anne Dougherty, Operations Director, Panacea Pharma Projects, Isle of Man.

Email: anne.dougherty@panacea.im; Tel: 44-1624 672777



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

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