

Public Health Link

from the Chief Medical Officer for Wales

Distribution:	As Appendix 2
From:	Chief Pharmaceutical Officer, Andrew Evans
Date:	7 November 2019
Reference:	CEM/CPhA/2019/33
Category:	Class 2: Action With 48 Hours
Title:	Class 2 Drug Alert, Action Within 48 Hours, Kyowa Kirin Limited, Mitomycin-C Kyowa 2mg, 10mg, 20mg, Powder For Solution For Injection; Mitomycin-C Kyowa 40mg, Powder For Intravesical Solution
For Action by:	<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>
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:

Kyowa Kirin Ltd is recalling all unexpired batches of the above product as a precautionary measure due to deviations from the aseptic manufacturing processes during the manufacture of the sterile active pharmaceutical ingredient and excipients.

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:**

Deputising services

HB Prescribing Advisers

Independent/Private clinics and Hospitals and Hospices throughout Wales



DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Hospital Pharmacy, Wholesaler Level Recall

Date: 07 November 2019

EL (19)A/33

Our Ref: MDR 121-09/19

Dear Healthcare Professional,

Kyowa Kirin Limited

Mitomycin-C Kyowa, 2 mg, powder for solution for injection.	PL 16508/0042
Mitomycin-C Kyowa, 10 mg, powder for solution for injection.	PL 16508/0043
Mitomycin-C Kyowa, 20 mg, powder for solution for injection.	PL 16508/0044
Mitomycin-C Kyowa 40 mg, powder for intravesical solution	PL 16508/0045

Brief description of the problem

Kyowa Kirin Ltd is recalling all unexpired batches of the above products as a precautionary measure due to deviations from the aseptic manufacturing processes during the manufacture of the sterile active pharmaceutical ingredient and excipients.

Advice for healthcare professionals

- Please immediately quarantine any units of these products which you have in your possession. Please return affected stock to your supplier using your suppliers approved process.
- Please see the Department of Health and Social Care and NHS England & Improvement, Supply Disruption Alert (**SDA/2019/006**) for further advice, including the use of unlicensed imports of mitomycin powder for solution for injection and intravesical solution.

Advice for Wholesalers

If you have supplied these products to any other wholesaler, please notify these wholesalers with a copy of this recall notice, requesting that they quarantine and return any unsold quantities of these products to you.



Company contacts for further information

For Stock enquiries please contact:

For Stock enquiries please contact:

Stuart Hay, Commercial Director

- Telephone: +44 (0) 1896 664045 / Mobile: +44 (0) 7968 983286
- E-mail: Stuart.Hay@kyowakirin.com

Iain Crolla, Commercial Manager

- Telephone: +44 (0) 1896 661661 / Mobile: +44 (0) 777 6748868
- E-mail: Iain.Crolla@kyowakirin.com

For Medical Information enquiries please contact:

- Medical Information Direct Line: + 44 (0)1896 664 000
- E-mail: medinfo@kyowakirin.com

For Quality information please contact:

Hazel Kennett (Responsible Person) on telephone number

- Telephone: +44 (0) 1896 664025 / Mobile: +44 (0) 7989 991831
- E-mail: Hazel.Kennett@kyowakirin.com

Martin Smith (Responsible Person)

- Telephone: +44 (0)1896 664030 / Mobile: +44 (0)7904 671 807
- E-mail: Martin.Smith@kyowakirin.com

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

Yours faithfully

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