



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:

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- E-mail: Stuart.Hay@kyowakirin.com

Iain Crolla, Commercial Manager

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- 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

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- E-mail: Hazel.Kennett@kyowakirin.com

Martin Smith (Responsible Person)

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- 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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