Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

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

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574