

Public Health Link

From the Chief Medical Officer for Wales

Distribution:	As Appendix 1
From:	Andrew Evans, Directorate of Health Policy
Date:	22 February 2018
Reference:	CEM/CPhA/2018/5
Category:	Class 4: For information
Title:	Drug Alert Class 4: Kyowa Kirin, Bleo-Kyowa Powder For Solution For Injection, 15,000 Iu, PI 16508/0046
What is this about:	Full details are set out below.
Why has it been sent:	For your information and to pass on to Colleagues

Issue:

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>

To: NHS Wales Shared Services Partnership to forward to:

All General practitioners - please ensure this message is seen by all practice nurses and non-principals working in your practice and retain a copy in your 'locum information pack'.

All Community Pharmacists

Deputising services

HB Chief Pharmacists

HB Prescribing Advisers

Independent/Private clinics and Hospitals and Hospices throughout Wales

To: Chief Executives of Health Boards

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

cc: Public Health Wales

Consultants in Pharmaceutical Public Health

Chief Executives, NHS Trusts

Principal Pharmacist Welsh Quality Control

Principal Pharmacist Continuing Care Services

Principal Pharmacist Welsh Medicines Information Centre

CSSIW

NHS Direct

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Distribute to Hospital Pharmacy, Ward, Chemotherapy Unit and Clinic Level

Date: 22/02/18

EL (18) A/05

Our Ref: MDR 147-09/17

Dear Healthcare Professional,

Kyowa Kirin

Bleo-Kyowa[®], Powder for Solution for Injection, 15,000 IU (Bleomycin sulfate)			PL 16508/0046
Batch Number	Expiry Date	Pack Size	First Distributed
X7B240	Sept 2020	10	Feb 2018

Brief description of the problem

- In April 2017, glass particles were detected in a batch of Bleo-Medac (bleomycin sulfate) from the same manufacturer.

Actions for healthcare professionals

- While investigations are ongoing, additional measures should be adopted, as follows:
 - Follow all the recommended steps for the preparation of Bleo-Kyowa in accordance with the [Summary of Product Characteristics](#).
 - Carefully inspect the reconstituted product under a bright light.
 - If particulate or glass matter is visible after reconstitution, do not administer the product to patients. Please retain the vial, quarantined safely away from other stock and notify the marketing authorisation holder (details overleaf).
 - If there is no visible particulate matter after reconstitution, **the use of a standard 5-micron (5 µm) filter needle to withdraw the reconstituted product from the vial prior to administration is recommended** as glass particles may be difficult to see.



Background

In April 2017, reports of glass particles in a batch of Bleo-Medac Powder for Solution for Injection, 15,000 IU, resulted in recall in some European countries. No recall action was necessary in the UK as the affected batch had not been distributed in the UK.

The marketing authorisation holder continues to investigate the root cause of this quality defect. To maintain continuity of supply in the UK, the marketing authorisation holder will distribute new batches of Bleo-Kyowa that meet current specifications. However, while investigations continue, the MHRA recommends that healthcare professionals adopt the following precautionary measures during product reconstitution:

- Follow all the recommended steps for the preparation of Bleo-Kyowa in accordance with the [Summary of Product Characteristics](#).
- Carefully inspect the reconstituted product under a bright light.
- If particulate or glass matter is visible after reconstitution, do not administer the product to patients. Please retain the vial, quarantined safely away from other stock and notify the marketing authorisation holder.
- If there is no visible particulate matter after reconstitution, **the use of a standard 5-micron (5 µm) filter needle to withdraw the reconstituted product from the vial prior to administration is recommended** as glass particles may be difficult to see.

Company contact details

If you have any questions about this letter or any other enquiry, please contact Kyowa Kirin Medical Information:

- Tel: +44 (0)1896 664000
- Email: medinfo@kyowakirin.com

Recipients of this Drug Alert should bring it to the attention of all relevant contacts involved with the supply and administration of chemotherapy, including: hospital pharmacists; hospital clinicians; ward staff; chemotherapy unit staff; nursing staff and clinic staff by copy of this letter. In addition, the relevant Healthcare Professionals should be informed where the product is being used in a domiciliary setting. Local area teams are asked to forward this to relevant clinics and hospital pharmacy departments.

Yours faithfully

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