Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

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

Date: 19th June 2018 EL (18) A/09 Our Ref: MDR 147-09/17

Dear Healthcare Professional,

Kyowa Kirin

Bleo-Kyowa®, Powder for Solution for Injection, 15,000 IU	**PL 16508/0046**
(Bleomycin sulfate)	

Batch Number	Expiry Date	Pack Size	First Distributed
Y7B290	Oct 2020	10	Jun 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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