

Kyowa Kirin Limited  
Galabank Business Park  
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United Kingdom

9 February 2018

## Direct Healthcare Professional Communication

**BLEO-KYOWA® (bleomycin sulphate), powder for solution for injection – use 5-micron filter during IV infusion or pre-injection**

| Batch Number | Expiry Date       | Pack Size | First Distributed |
|--------------|-------------------|-----------|-------------------|
| X7B240       | 30 September 2020 | 10        | Feb 2018          |

Dear Healthcare Professional,

Kyowa Kirin Limited, in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) advises that:

- Although we have no current evidence in the UK of glass particle contamination of Bleo-Kyowa (bleomycin sulphate), while investigations continue, we recommend you:
  1. Follow all the recommended steps for the preparation of Bleo-Kyowa in accordance with the Summary of Product Characteristics
  2. Carefully inspect the reconstituted product under a bright light.
  3. If particulate or glass matter is visible after reconstitution, do not administer the product to patients, retain the vial for collection, and notify the MHRA via the Yellow Card Scheme and inform the marketing authorisation holder (details below).
  4. If there is no visible particulate matter after reconstitution, **the use of a standard 5-micron filter needle to withdraw the reconstituted product from the vial prior to administration is recommended** as glass particles may be difficult to see.

## Background on the safety concern

Kyowa Kirin Limited has been advised of a recent contamination of bleomycin sulphate with glass particles in a batch distributed elsewhere in Europe from the same manufacturer. Vials released to the UK market meet all release specifications. However, while investigations continue, we recommend healthcare professionals inspect vials and use an appropriate filter.

## Call for reporting

Suspected adverse drug reactions, including medicines thought to be defective, should be reported via the Yellow Card Scheme website <https://yellowcard.mhra.gov.uk/>, on the Yellow Card app, or by emailing [yellowcard@mhra.gov.uk](mailto:yellowcard@mhra.gov.uk). Adverse events may also be reported to [medinfo@kyowakirin.com](mailto:medinfo@kyowakirin.com) or on tel. +44 (0)1896 664000.

Yours sincerely,



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