Feb 2025

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Emblaveo® (aztreonam/avibactam) 1.5 g/0.5 g powder for concentrate for solution for infusion: potential for cracked or broken vials (PLGB 00057/1721)

Dear Healthcare Professional,

PFIZER LIMITED in agreement with the MHRA, would like to inform you of the following:

SUMMARY

Pfizer has identified broken or cracked glass vials in distributed batches of Emblaveo 1.5g/0.5g powder for concentrate for solution for infusion. Refer to Table 1 below for batches currently in circulation that are potentially impacted.

- **Visually inspect all Emblaveo glass vials upon receipt of this letter paying special attention to the potential for damage.**
- **Do not use the vial of Emblaveo if the glass is damaged. As with any damaged vial, the potential risk to product integrity cannot be ruled out.**
- **Should you identify a damaged glass vial, please report this as a product complaint and send a photograph of the damaged glass vial to Pfizer (see Company Contact Point below).**
- **If the glass vial is not damaged, continue with the reconstitution and dilution process as per instructions in the product information.**

BACKGROUND

Emblaveo is a combination antibiotic used in the treatment of adult patients with acute and potentially life-threatening infections. Emblaveo is indicated for the treatment of the following infections in adult patients:

- complicated intra-abdominal infection;
- hospital acquired pneumonia, including ventilator associated pneumonia, and;
- complicated urinary tract infection, including pyelonephritis.

It is also indicated for the treatment of infections due to aerobic Gram-negative organisms in adult patients with limited treatment options (see sections 4.2, 4.4 and 5.1 of the summary of product characteristics).

Emblaveo is available as a freeze-dried powder in a 30 mL glass vial. The powder must be reconstituted with sterile water for injections and the resulting concentrate must then be immediately diluted prior to use. The reconstituted solution is a clear, colourless to yellow

solution and is free of visible particles. Standard aseptic techniques should be used for solution preparation and administration.

Pfizer received confirmed complaints of broken vials of Emblaveo. An investigation was initiated, which included review of batch filling, lyophilization and packaging processes, and laboratory analysis of the glass vials. The root cause for the damage to the glass vials was attributed to glass-to-glass contact of the 10 pack vials during handling activities on the packaging line coupled with insufficient support from the glued carton partitions (automated packaged vials) or absence of carton partitions (for hand-packed vials) within the secondary carton.

As part of the investigation, retain and reference samples from all distributed batches of Emblaveo and batches that were still in control at the manufacturing site were inspected. The rate of occurrence of the defect was low at 0.03%.

Refer to Table 1 below for a list of potentially affected batches of Emblaveo currently in circulation (including batches distributed, partially distributed and/or under Pfizer control) in the UK.

Healthcare professionals must visually inspect each vial upon receipt of this letter. If damage to the vial is observed, it should not be used. Additionally, the damaged vial should be reported as a product complaint via the Company Contact Point below.

To date, Pfizer has not received any reports of adverse events related to broken or cracked vials.

Table 1. List of batches currently in circulation in the UK

Country	**Batch number**
United Kingdom	LC7424AB

CALL FOR REPORTING

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store

- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.
When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Please continue to report any suspect adverse drug reactions to www.pfizersafetyreporting.com

COMPANY CONTACT POINT

Alternatively, suspected adverse reaction may also be reported to the Marketing Authorisation Holder using the details provided below. If you have further questions or require additional information, please contact:

Company	**Product name**	**Email**	**Phone**
Pfizer Ltd	Emblaveo	medical.information@pfizer.com	01304 616161

Yours sincerely,

Seema Patel
Specialty Care Medical Director
Pfizer UK