MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(26)A/39

Caution In Use

Issued 23 September 2026

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

B. Braun Melsungen AG

MEDICINE DETAILS

Meropenem 1000 mg powder and solvent for solution for infusion

PL: 03551/0167
Active Ingredient: meropenem
SNOMED code: 44947011000001108 (24 pack)
GTIN: 4030539225526 (24 pack)

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
25J00360	31/10/2026	24	20/06/2025
25J01305	31/01/2027	24	Not yet distributed
25J02333	31/03/2027	24	12/01/2026
25J02595	31/03/2027	24	Not yet distributed
25J02331	31/03/2027	24	Not yet distributed
25J02332	31/03/2027	24	Not yet distributed
25J02335	31/03/2027	24	Not yet distributed

Background

B. Braun Melsungen AG has notified the MHRA that errors have been identified in the Patient Information Leaflet (PIL) included in some batches of Meropenem 1000 mg powder and solvent for solution for infusion. The PIL provides incorrect information regarding the sodium content and product strength in the sections outlined below. Currently all available stock contains the affected version of the PIL.

To minimise the risk of supply disruption, certain batches that have not yet been distributed are also included in this notification. Following discussions between the MHRA and the Department of Health and Social Care, these products have been considered critical for patients. Therefore, the affected batches will continue to be supplied without repackaging and are included in this notification.

In section 2 the sodium content was reflected incorrectly:

Incorrect information	Correct information
Meropenem contains sodium This medicinal product contains 245 mg sodium (main component of cooking/table salt) per bag, equivalent to 12.3 % of the recommended maximum daily dietary intake of sodium for an adult. If you have a condition which requires you to monitor your sodium intake, please inform your doctor or pharmacist.	Meropenem contains sodium This medicinal product contains 290 mg sodium (main component of cooking/table salt) per bag, equivalent to 14.5 % of the recommended maximum daily dietary intake of sodium for an adult. If you have a condition which requires you to monitor your sodium intake, please inform your doctor or pharmacist.

In the section 6 the strength of the product was stated incorrectly:

Incorrect information	Correct information
What Meropenem contains The active substance is meropenem. One two-chamber bag contains meropenem trihydrate equivalent to 500 mg anhydrous meropenem. The other ingredients are sodium chloride, water for injections and sodium carbonate.	What Meropenem contains The active substance is meropenem. One two-chamber bag contains meropenem trihydrate equivalent to 1000 mg anhydrous meropenem. The other ingredients are sodium chloride, water for injections and sodium carbonate.

All information on the Label and in the SmPC is correct and all other sections in the PIL are also correct.

Advice for Healthcare Professionals:

Healthcare professionals are advised to continue using B. Braun Meropenem 1000 mg powder and solvent for solution for infusion in accordance with the approved Summary of Product Characteristics (SmPC). Although section 6 of the Patient Information Leaflet (PIL) incorrectly refers to 500 mg, the correct strength (1000 mg) is stated on the product packaging and in the relevant PIL heading.

The identified issue is limited to incorrect information within sections 2 and 6 of the PIL, relating to the stated sodium content and product strength respectively. The issue does not affect the quality of the physical product formulation or efficacy of the medicinal product.

Healthcare professionals are advised to review the information contained within this notification and take this into account when dispensing or administering this product, especially for new patients.

Upon request, B Braun will provide hard copies of the updated PIL to wholesalers and pharmacies so that any packs can be supplemented with the correct PIL information. To request hard copies of the PIL, please contact medinfo.bbmuk@bbraun.com, or telephone 08002980299 with your details, i.e. address, product with batch details, required number of leaflets.

Advice for Healthcare Professionals to Provide to Patients:

Patients should continue to take medicines from these batches as administered by your healthcare professional. This does not affect the quality of the solution for infusion.

If patients have concerns or questions, they should contact their Outpatient Parenteral Antimicrobial Therapy (OPAT) team in the first instance. Do not stop taking your medication without speaking to healthcare professionals involved in your treatment.

Patients who experience adverse reactions or have any questions about their medication should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

Additional information:

For medical information enquiries, please email medinfo.bbmuk@bbraun.com, or telephone 08002980299.

For stock enquiries please email recalls.uk@bbraun.com, or telephone 0114 2259155

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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