

MEDICINES RECALL

CLASS 2 MEDICINES RECALL, EL(25)A/22 Action within 48 hours

Issued 19 May 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Becton Dickinson UK Ltd

MEDICINE DETAILS

BD ChloraPrep Clear - 1mL Applicator

PL: PL 05920/0002

Active Ingredient: chlorhexidine gluconate 2%w/v and isopropyl alcohol 70% v/v

SNOMED code: 40818011000001105

GTIN: 20885403491761

AFFECTED LOT BATCH NUMBERS

| Batch No. | Expiry Date | Pack Size | First Distributed |
|-----------|-------------|----------------|-------------------|
| 4099824 | 30-Apr-27 | 60 applicators | 18/07/2024 |
| 4099828 | 30-Apr-27 | 60 applicators | 24/07/2024 |
| 4108755 | 30-Apr-27 | 60 applicators | 15/08/2024 |
| 4108759 | 30-Apr-27 | 60 applicators | 11/09/2024 |
| 4116445 | 30-Apr-27 | 60 applicators | 30/07/2024 |
| 4120316 | 30-Apr-27 | 60 applicators | 05/08/2024 |
| 4120319 | 30-Apr-27 | 60 applicators | 12/08/2024 |
| 4121513 | 30-Apr-27 | 60 applicators | 14/08/2024 |
| 4121515 | 30-Apr-27 | 60 applicators | 14/08/2024 |

| 4255105 | 30-Sep-27 | 60 applicators | 24/02/2025 |
|---------|-----------|----------------|------------|
| 4255107 | 30-Sep-27 | 60 applicators | 06/01/2025 |
| 4255108 | 30-Sep-27 | 60 applicators | 17/02/2025 |
| 4257774 | 30-Sep-27 | 60 applicators | 23/01/2025 |
| 4257778 | 30-Sep-27 | 60 applicators | 23/01/2025 |
| 4257776 | 30-Sep-27 | 60 applicators | 13/01/2025 |
| 4257777 | 30-Sep-27 | 60 applicators | 20/01/2025 |
| 4259473 | 30-Sep-27 | 60 applicators | 13/01/2025 |
| 4275220 | 31-Oct-27 | 60 applicators | 19/02/2025 |
| 4276062 | 31-Oct-27 | 60 applicators | 03/03/2025 |
| 4276059 | 31-Oct-27 | 60 applicators | 19/02/2025 |
| 4276075 | 31-Oct-27 | 60 applicators | 19/02/2025 |
| 4276079 | 31-Oct-27 | 60 applicators | 10/03/2025 |

Background

Becton Dickinson UK Ltd has informed the MHRA that some units exhibit an open seal on the packaging of the applicator. This defect could increase the risk of the applicator device being contaminated with pathogens, which could lead to increased infection rates for the patients.

The number of impacted units in each batch is unknown, therefore the batches included in the table above are being recalled as a precautionary measure. This recall does not impact other batches of BD ChloraPrep™ Clear - 1mL Applicator that remain available for clinical use.

Advice for Healthcare Professionals:

Stop supplying the affected batches. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

Advice for Healthcare Professionals to Provide to Patients:

No further action is required by patients as this product is used by healthcare professionals only and they will have taken the action to remove this product from use.

The recall is a precautionary measure to mitigate any additional risk of infection.

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 all medical information enquiries and information on this product, please email safetyinformation@bd.com, or telephone 08000437546.

For stock control enquiries please email <u>info@insightbio.com</u>, or telephone 01707351330.

Recipients of this Medicines Recall 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

Defective Medicines Report Centre

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