

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

4121513

4121515

AFFECTED LOT BATCH NUMBERS Batch No. **Pack Size First Distributed Expiry Date** 4099824 30-Apr-27 60 applicators 18/07/2024 24/07/2024 4099828 30-Apr-27 60 applicators 30-Apr-27 4108755 60 applicators 15/08/2024 4108759 30-Apr-27 60 applicators 11/09/2024 4116445 30-Apr-27 60 applicators 30/07/2024 4120316 60 applicators 30-Apr-27 05/08/2024 4120319 60 applicators 12/08/2024 30-Apr-27

60 applicators

60 applicators

14/08/2024

14/08/2024

30-Apr-27

30-Apr-27

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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