MEDICINES RECALL

CLASS 2 MEDICINES RECALL, EL(26)A/15

Action within 48 hours

Issued 23 March 2026

Distribute to Pharmacy/Wholesaler/Retail Level

MARKETING AUTHORISATION HOLDER (MAH)

Regent Medical Limited / Mölnlycke Health Care

MEDICINE DETAILS

Hibiwash 500ml

PL: 22099/0003

Active Ingredient: chlorhexidine gluconate 4%

SNOMED code: 42773211000001109

GTIN: 07333350300401

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
5156042	28/11/2028	500ml	10/02/2026
5156043	28/11/2028	500ml	10/02/2026
5156093	28/11/2028	500ml	10/03/2026

Background

Mölnlycke Health Care are recalling specific batches of Hibiwash due to microbial contamination at the manufacturing facility, following routine weekly microbiological monitoring. The microbial contamination has been identified as *Burkholderia cepacia*. The investigation is ongoing, and to date no Hibiwash products have been found to be contaminated, however the batches at risk of contamination are being recalled as a precaution to mitigate any risks to public health.

Burkolderia cepacia is a gram-negative bacteria that is widely found in the environment, including soil and water, and has intrinsic resistance to many antibiotics. The risk to the

general public from *Burkholderia cepacia* is considered very low, but some patient groups (such as individuals with cystic fibrosis or awaiting lung transplant) are at potentially increased risk of developing infections.

The use of the batches specified in this notification should be avoided. There have currently been no confirmed cases of *Burkholderia cepacia* infection in patients from the affected batches.

This product is also typically provided to patients pre-surgery for decolonisation and prevention of *Staphylococcus aureus* skin and soft tissue infections, and can be used for pre-operative surgical hand disinfection. Recommended precautionary measures for healthcare professionals, retailers and patients are set out below.

Advice for Healthcare Professionals and retailers:

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

Healthcare professionals responsible for the management of patients with cystic fibrosis or awaiting lung transplant who have been supplied with Hibiwash since 10 February 2026 should contact patients directly.

- If they have product from the impacted batches, please advise them to return it to the place of supply or sale, or a pharmacy for disposal. Please reassure the patient this is a precautionary measure and the risk is low. Advise them that should they develop symptoms consistent with infection, such as a high temperature (fever), they should contact their clinical team for advice and seek medical attention. Please provide an alternative product following local procedures.

There is no need to contact other patients. If you are contacted by a member of the public or patient who suspects they have used a product from an affected batch, they should be reassured that risk is very low.

- Please advise patients to return any product from the implicated batches to the place of supply or sale, or a pharmacy for disposal. Advise them if they have symptoms of infection such as fever they should seek medical attention.

Hibiwash is a General Sales List (GSL) product and may be available in retail stores and online; this advice applies to all settings where the product is sold. This product is often procured as a stock item and available in various health and care settings and the impacted batches should be quarantined and returned to the supplier/procurement team in the first instance.

- Healthcare professionals (including those in pharmacy, dental, ambulance and other retailer sectors), along with supply teams for this product should consider local, co-ordinated arrangements to stop using the impacted products and source alternative products.

Please provide support to source an alternative product if/as appropriate following local procedures. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

Advice for Patients or customers who have purchased the impacted batches:

This recall is for Hibiwash 500ml and impacts batches 5156042, 5156043 and 5156093 only. The batch number can be found on the bottle. The batches specified in this notification are being recalled as precautionary measure, no reports of patient harm have been received from patients relating to this defect.

If you have received the impacted batch, do not use the product.

- If you have been prescribed/provided this product by a healthcare professional, please contact them and request an alternative.
- If you have purchased this product yourself, please note that alternative chlorhexidine gluconate 4% washes are available from other manufacturers and are not impacted by this recall.
- If you develop signs and symptoms of infection such as fever, seek medical attention.

Patients who experience adverse reactions or have any questions about the 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 use contact: Vigilance@molnlycke.com or telephone: +46 31 722 30 00. For stock queries please contact: UK Responsible Person: mohammad.humadi@molnlycke.com

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

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