

GAMA Healthcare Ltd.

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Ref: CAPA-2021-07
MHRA Ref: 2021/005/005/601/530
26/07/2021

Clinell Universal Wipes – Urgent recall – UPDATE
REF CW200

Updates are highlighted in Bold

Updated Lot numbers UBV3032520A, UBV3032520B, UBV1032720A & UBV7032720A

Original Lot numbers UBV1033020A, UBV2033020A, UBV3033020A, UBV4033020A,
UBV6032920A,

ISSUE

Recent, routine testing of **nine** Lots/batches of Universal Wipes, REF CW200 manufactured in one of our smaller factories has identified contamination with ***Burkholderia contaminans***.

B. contaminans is a Gram-negative bacilli, that belongs to Taxon K (group K) of the *Burkholderia cepacia* complex (Bcc) and is found widely in the natural environment including soil and water.

Described as ‘opportunistic pathogen’ *B. contaminans* poses little medical risk to healthy individuals but can cause serious infections in those with compromised immune systems notably individuals with cystic fibrosis and chronic granulomatous disease. Bcc is a known cause of infections in hospitalised patients, particularly those with weakened immune systems, spread by person to person contact or contact with contaminated surfaces.

Treatment of individual infections with Bcc present a challenge as it is often resistant to many of the more commonly used antimicrobials. Over the last couple of decades, outbreaks of Bcc infection have been linked to contaminated environments, devices, solutions and medications.

GAMA Healthcare are initiating an immediate recall of the batches identified whilst continuing the ongoing investigations.

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The originally identified five batches were manufactured in July 2020 and were distributed between 11th September and the end of December, 2020. **The updated batches were manufactured on three days June, 2020 and were distributed between 31st July, 2020 and 4th November, 2020.** If GAMA supplied you directly, you will receive a direct communication with specific dates, order numbers and Lot details to allow simpler product identification. If you were supplied through an NHS central system in the UK, your MDSO will have received this notice.

ACTION

Please identify and isolate any of this batch of wipes remaining in stock or issued within your organisation. The LOT number is printed in black on the top edge of the pack, above the expiry date. For cartons, the Lot number is printed on a label on the side of the box. Once isolated, please complete the attached form and return to GAMA as soon as possible but, in any case, no later than the **20th August, 2021.**

GAMA Healthcare would prefer for you to destroy any identified stock, but we can coordinate return and destruction if needed. A credit will be issued upon return of the attached Return Notice.

For any queries about this recall, please contact GAMA Regulatory Team;

Regulatory@gamahealthcare.com, or by calling GAMA by phone on +44 (0) 207 993 0030 and selecting the Regulatory option from the menu.

A handwritten signature in blue ink, appearing to read 'G. Milward'.

Graham Milward
Deputy Regulatory Affairs & Quality Assurance Director
GAMA Healthcare Ltd