
Field Safety Corrective Action

UMONIUM38® MEDICAL SPRAY 1L

FSCA: 2021-01

PRODUCTS RECALL

Date: 01/27/2021

For the attention of all users and operators.

Dear customer,

Following a non-conformity of our **UMONIUM38® Medical Spray 1L** product (reference PF12209), we are proceeding to a voluntary recall of all products with batch numbers beginning with **20K04** (complete list in annex 1).

Indeed, these products have been released in accordance with our quality specifications. However, during a control a few weeks later by an external body, according to our quality procedure, we found that these products were non-compliant in terms of the percentage of active substance and a decrease in performance over time.

This issue is still under investigation and only concerns UMONIUM38® Medical Spray products 1L whose batch number starts with 20K04.

Therefore, we ask you **to identify and isolate** all products concerned that are not used or in use.

We then ask you **to return the product return form** (appendix 2) to us in order to proceed with the return of the affected products in our premises for destruction.

There is no additional action to be taken for products already used.

This safety information must be transmitted to any appropriate person in your establishment or to any establishment where the products concerned have been potentially transferred.

The competent authority has been informed of this safety information.

We would like to express our sincere apologies for the inconvenience caused. Every effort is being made to ensure that this problem does not recur.

Our values of ethics and consistent quality remain rooted in every member of Laboratoire Huckert's International and to this day every step is reviewed and certified to meet the high standards we set for ourselves.

All of our teams are at your disposal for any questions or assistance.

We thank you for your collaboration.

Please accept, Madam, Sir, the expression of our best regards.

Florence Huckert

CEO

Laboratoire Huckert's International



ANNEX 1: Complete list of affected batch numbers

Affected batch numbers
20K04K23K23
20K04K24K30
20K04K27K27
20K04K30K30
20K04K30K30R
20K04L01L01
20K04L01L01R

ANNEX 2 : Acknowledgement of receipt and product return form

Please complete this form and return it by email to info@huckerts.net before **26 February 2021**.

Upon receipt of this form, Laboratoire Huckert's International will register the correct receipt of the safety information and will proceed to the return of the products concerned.

Thank you to fill in this form even if you no longer have the products concerned in stock and to specify "0" on the last line.

Company name :

Contact name filling in
the form :

Address :

Postal code :

City :

Country :

Phone number :

E-mail address :

Date of receipt of the
safety notice :

Number of affected
products to return :

We acknowledge receipt of the security information FSCA no. 2021-01, and confirm that we have received the following taken note.

Date

Signature

Stamp

