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Important Field Safety Notice

Product Recall
of certain batch of Artelac® Rebalance
Eye Drops

Sender:
Dr. Gerhard Mann chem.-pharm. Fabrik GmbH
Brunsbuetteler Damm 165/173
13581 Berlin
Germany

Berlin, 23-April-2021

Batch recall: Artelac® Rebalance (batch: LOT 520) German/French/Dutch Language Labelling Only
Product category: Medical Device, Eye lubricant and contact lens wetting
Type of action: Recall of affected Artelac Rebalance products

Dear Sir or Madam,

We would like to inform you of a precautionary batch recall of Artelac Rebalance.

Please note that this batch recall is a recall of a part of your stock. A health risk for the end user is not expected.

Description of the problem and product information
The product recall for the affected batch is due to the incorrect shipment of products intended for the Belgian market to the UK/Ireland markets. As a result part of the shipments for batch 520 of Artelac Rebalance contain products with German/French/Dutch labelling. The labelling and Instructions for Use should be understood by all users in their country official language. Therefore German/French/Dutch labelled products must not be distributed in UK or Ireland.

The safety of the product itself is not affected and no negative effect is expected, if used.

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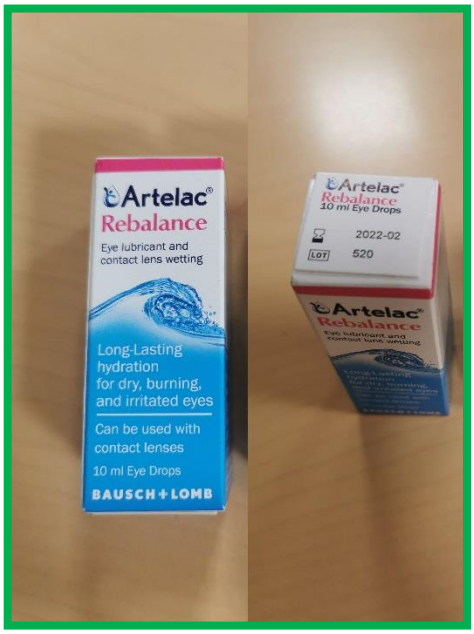
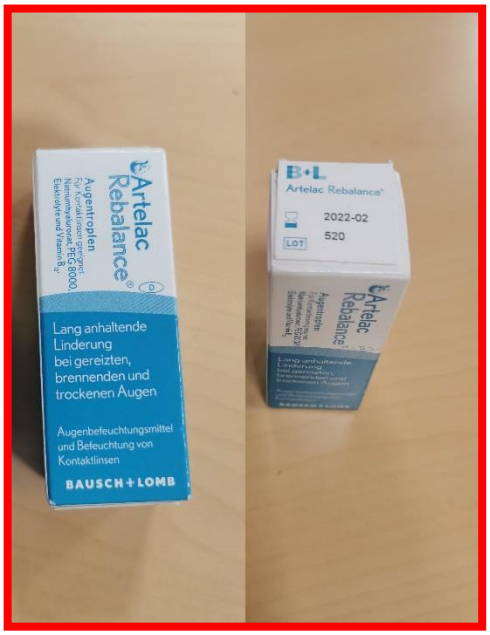
How to distinguish the products?
Only batch LOT 520 of Artelac Rebalance is affected. Batch number and expiry date are identical for UK/Ireland and Belgium Products, however the packaging and language is different.

- Products for the UK/Ireland markets are packed in a red and blue box with English labelling. These products are correct and can be sold.
- Products intended for Belgium are packed in a blue box only with German, French and Dutch language labelling. These products must be quarantined.



Correct



Incorrect product, affected by this recall

Example of the product label:
Left-hand side: red and blue box for UK / Ireland (English labelling);
Right-hand side: blue box only intended for Belgium (German/French/Dutch labelling)
The batch number information is located on the upper flap of the package.

Measures to be taken:

1. **Quarantine or separate the product:**
   - Please count and separate the cartons of batch No: LOT 520.
   - Please check the labelling of the products: red and blue box with English labelling (correct) or blue box only with German/French/Dutch labelling (incorrect, to be quarantined)
   - Affected products with German/French/Dutch language labelling must be quarantined.
   - Check, how many products of affected batch LOT 520 already have been distributed
   - Complete the Artelac Rebalance Quarantine Confirmation Form with the number of units affected (Annex 1).

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- Please fill out the form stating zero balance, even if you don't have any affected products in your stock.
- The form shall be sent to Customer Services email box: Pharma_CS@bausch.com as soon as possible, but no later than 30-April-2021.

2. Return of the Product

- After receiving the completed confirmation form Customer Services will contact you in order to organise the return of the quarantined products.

Please make sure that all persons to be informed in your organisation are aware of this recall information. Please retain this information at least until the action has been completed.

The decision to carry out this product recall is part of our commitment to quality and satisfaction of our customers. We apologise for any inconvenience and assure you that we are working hard to complete this recall as soon as possible.

If you have any questions, please contact us:
Email: Pharma_CS@bausch.com

Phone: 0845 602 2350

Best Regards

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ANNEX 1

CONFIRMATION FORM FOR THE QUARANTINE OF
Artelac® Rebalance, Batch LOT 520

With this form you confirm the receipt of the recall notification of 23-April-2021 in your facility.

Product details: Artelac Rebalance, batch LOT 520, manufactured by Dr. Gerhard Mann chem.-pharm. Fabrik GmbH and affected by precautionary product recall.

We kindly ask you to confirm if there are any products with the affected batch number in your stock. Please check the labelling and confirm the language on the labelling.
Immediately Quarantine all products with German/French/Dutch language labelling.

Article	Affected batch/LOT number	Language of the labelling	Number of units In your Stock or Distributed
Artelac Rebalance	520	English (red and blue box)	
Artelac Rebalance	520	German / French / Dutch (only blue box)	
Artelac Rebalance	520	Already distributed to pharmacies / customers	

☐ **I hereby confirm that the above mentioned products with German/French/Dutch language labelling have been quarantined as a precautionary measure.**

☐ **I hereby confirm that none of the above mentioned products are in our stock.**

Wholesaler / Health care facility: Customer No:

City Code/ City: E-Mail:

Surname and first name:

Signature: Date:

Please return the completed and signed confirmation form by e-mail to: Pharma_CS@bausch.com

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