

To the attention of Distributor

Neuville-sur-Oise, March 15th, 2023

Internal reference: FCA# 32

Product Information - FIELD NOTICE

Revohem™ Arachidonic acid - Ref BV413997- Lot FB0459

Packaging problem with the Revohem™ Arachidonic acid boxes

Dear customer,

Our traceability indicates that you have received the following product:

Name	Reference	Lot
Revohem™ Arachidonic acid	BV413997	FB0459

➤ **Problem description**

Following a complaint on Revohem™ Arachidonic acid, reference BV413997, lot FB0459, and our internal investigations, we confirmed that some Revohem™ Arachidonic acid kits of lot FB0459 were packaged in a pre-printed box of Revohem™ ADP. However, vials and instruction for use in the box are clearly identified as Revohem™ Arachidonic acid as well as the side box label. This issue was randomly identified and does not affect the entire lot FB0459.

➤ **Risk analysis and impacts**

Vials of Revohem™ Arachidonic acid product lot FB0459 are correctly labelled: product name, lot, and expiration date. The product label stamped on the side of the box is also compliant. The instruction for use (IFU) inside the box also corresponds to the Revohem™ Arachidonic acid.

Based on this information, the error of identification is judged as minor and will be detected by the end user as the vials and IFU are clearly identified. Besides, the verification of the lot number and the reading of the IFU must be done before each use according to the good laboratory practices.

Therefore, the **probability of occurrence** of the use of the Revohem™ Arachidonic acid with Revohem™ ADP protocol is **very rare**.

The **consequence** of this use is qualified as **minor and without incidence in terms of medical decision** as soon as IFU recommendations and good clinical practices are respected.

➤ **Actions to be implemented**

1. By the distributor:

- Notify the Field Notification to all concerned end users.

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Address: ZAC Neuville sur Oise – 155 rue d'Eragny – 95000 NEUVILLE SUR OISE (France)
Tel: +33.1.34.40.65.10 ♦ Fax: +33.1.34.48.72.36 ♦ Web Site : <http://www.hyphen-biomed.com>

HYPHEN BioMed, SAS au Capital de 1 427 820 Euros
RCS Pontoise : B 421 645 979 - N° SIRET : 421 645 979 00038 - APE : 2120Z - TVA : FR 40 421 645 979

- For the products remaining in your stock, please proceed to a visual check before the shipment: Check if there are no labels with the name ADP on the box (on top and front side). The compliant boxes can be put on the market.
- Destroy Revohem™ Arachidonic acid lot FB0459 with Revohem™ ADP box labeling and specify the destroyed quantity.
- Please complete and return the Awareness Acknowledgment Form to HYPHEN BioMed: VigilanceHBM@hyphen-biomed.com.

2. By the end-user:

- Destroy Revohem™ Arachidonic acid product with Revohem™ ADP box labeling and specify the destroyed quantity.
- Compliant boxes can be used.
- Complete and return the Awareness Acknowledgment Form to your local distributor.

We apologize for any inconvenience this may cause and remain at your disposal.

Sincerely yours,

Diane Agnandji BELEI
Regulatory Affairs and Quality Assurance Director



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