

ION* Sinus Support Recall

Dear ION* Community,

This is to inform you of a product recall involving:

ION* Sinus Support, ION* Biome Sinus, and Restore Sinus Spray, all lots

Biomic Sciences is voluntarily recalling all lots of ION* Sinus Support, ION* Biome Sinus, and Restore Sinus Spray products. FDA testing found the product to contain microbial contamination identified as *Microbacterium sp., Fictibacillus sp., Bacillus sp., (primarily B. malikii),* and *Paenibacillus sp* (these microorganisms are generally non-pathogenic).

Biomic Sciences has not received any reports of adverse events related to this product. However, in the population most at risk, patients or individuals who recently underwent nasal or sinus surgery, there is a possibility that the use of the affected product could potentially result in severe or life-threatening adverse events such as bacteremia or fungemia, invasive bacterial or fungal rhinosinusitis, or disseminated fungal infection.

All lots of the of the following products are covered by this recall:



ION* Sinus Support

Sales Period:
September 2021
through
September 20, 2023



ION* Biome Sinus

Sales Period: September 2019 through September 2021



Restore Sinus Spray

Sales Period:
June 2017
through
September 2019

Immediately examine your inventory and quarantine product subject to recall.

Please complete and submit this response form as soon as possible. You may request a refund of remaining ION* Sinus inventory through this same linked form.

This recall should be carried out to the user level. If you have further distributed this product, please identify your customers/clients, and notify them at once of this product recall. Your notification to your customers/clients may be enhanced by including a copy of this recall notification letter. Please advise all customers/clients to stop using the product. Customers/clients should dispose of any remaining ION* Sinus product. However, if they would like a refund, they should take a picture of the batch number on the bottom of the bottle before disposing of it.

You may refer your customers to Biomic Sciences (contact information provided below) or to our <u>consumer information page</u> to submit for a refund. Please note refunds will take 6-8 weeks to process.

Your assistance is appreciated and necessary to prevent any potential inadvertent harm.

If you or your customers have any questions or concerns, please contact our ION* Sinus Support Recall Team at 1.844.715.0113 or sinusrecall@intelligenceofnature.com.

This recall is being made with the knowledge of the Food and Drug Administration.

We are truly sorry to relay this news and we are here to support you in any way we can.
Sincerely,
ION* Sinus Support Recall Team