Important Product Safety Notice
FSN_2025_01_Users

Medical Device Recall
Peroxide Disinfecting System 3% for contact lenses
Some neutralizing tablets may not be properly neutralizing the solution

Date: 03 JUN 2025
Company: DISOP S.A.
SRN: ES-MF-000001769

Dear user:

We are contacting you to inform you of an important safety notice regarding a contact lens care product you may be using. This notice concerns the peroxide disinfecting system with neutralizing tablets, intended for the daily cleaning and disinfection of all types of contact lenses (conventional, soft, disposable, silicone hydrogel, and RGP lenses). The brand names and impacted lots are listed in Annex 1 of this letter.

What happened?

We have received a series of complaints from users who experienced symptoms such as burning, redness, itching, stinging, inflammation, hyperemia, blurred vision, and pain after using the product.

During the investigation, it was found that in some cases the neutralizing tablets may not function as intended, resulting in incomplete neutralization of the disinfecting solution. In such cases, users may experience eye discomfort including the symptoms mentioned above.

The health and safety of everyone who uses our products is our top priority, and although no serious incidents with permanent injuries have been reported, we have decided to voluntarily recall certain lots of the peroxide system as a precautionary measure.

As a **precautionary measure**, we are informing you and requesting that you check whether you are in possession of any affected lots. (See Annex 1)

What should I do if I use this product?

1. **Locate the lot number** on the product packaging. Check the list of impacted lots in Annex 1 of this letter.
2. **If you have any of the affected products**:
    - **Stop using it immediately**.
    - **Do not dispose of the product.** Store it separately from other products.
    - Contact the place where you purchased it.
3. **If you have recently used the product** and are experiencing any eye discomfort:
    - Rinse your eyes thoroughly with sterile saline solution or artificial tears.
    - Contact your eye care professional (optician or ophthalmologist).
4. **If you have already used the product** without experiencing any discomfort:
    - No action is required.

Who can you contact?

Contact the place where you purchased the product.

If you have any questions, need assistance, or wish to report something related to the impacted product, you can email us at **recall@disop.com**. Please include the reference “FSN_2025_01 *Peroxide_User*” in the subject line of your message.

📧 **recall@disop.com**

Thank you for your cooperation and understanding. DISOP is working to fully clarify what happened and to take all necessary measures to prevent it from happening again.

This notice has also been reported to the appropriate health authorities, in accordance with the Medical Device Regulation (EU) 2017/745.

Please, keep this Letter next to the product and ensure it is shared with anyone else who may be using it.

Sincerely,

Firmado por:

María Paños

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María Paños Correas
Regulatory Compliance Officer (PRRC)

DISOP S.A.