
Soflens (Pty) Ltd.

Reg. No. 1968/011787/07

254 Hall Street, Centurion, 0157

PO Box 11418, Die Hoewes, 0163

T +27 (10) 025 2100 | F 086 432 3354

W www.bausch.co.za

URGENT MEDICAL DEVICE RECALL CLASS II TYPE A

BAUSCH + LOMB ANNOUNCES RECALL OF CERTAIN LOTS OF CONTACT LENS SOLUTIONS AND EYE LUBRICANTS

No Known Serious Adverse Events Related to this Recall

South Africa, May 24, 2021 - Bausch + Lomb, a leading global eye health business, is conducting a recall of certain lots of Biotrue® Multi-Purpose Solution, Boston® Advance Cleaner, Boston® Advance Conditioning Solution, Boston® Simplus Multi-Action Solution, EasySept® Peroxide Solution, Lens Lubricant®, ReNu® Multi-Purpose Solution, ReNu® MultiPlus Solution and Saline Plus® Solution that were manufactured at its facility in Milan, Italy. A complete list of the Bausch + Lomb products and lots impacted by this recall is below.

This voluntary recall is being conducted in Europe, Middle East, Africa, Russia/CIS, Hong Kong and China.

This recall follows a notification received by Bausch + Lomb from one of its third-party suppliers in Milan, Italy, which sterilizes some components (bottles, plugs, and caps) of these products prior to manufacturing in our facility in Milan, Italy, of a compliance issue with its sterilization process. Bausch + Lomb is one of many companies impacted by this situation.

While there is a low risk of infection with these products, we have chosen to voluntarily recall these certain lots of products because we cannot confirm the supplier's conformance to process compliance requirements for some of the components of these products. No serious adverse events have been reported to date in association with this issue.

Affected product lot information can be located at BLRecall.expertinquiry.com. No other Bausch + Lomb products or lots are affected by this recall.

Consumers who may have these affected products in their possession should take the following steps:



1. Visit BLRecall.expertinquiry.com to verify the product is impacted.
2. If the product is impacted, stop using the product.
3. Register for further instructions at BLRecall.expertinquiry.com.
4. After following all instructions, discard the impacted product.




For more information on the recall or for assistance with registration, consumers should contact Sedgwick, the firm conducting this product recall on behalf of Bausch + Lomb, via email: BLRecall@Sedgwick.com, phone: 080 099 4885 between the hours of 10:00 to 19:00 local time, Sunday – Saturday, or online at BLRecall.expertinquiry.com.




To report an adverse event or complaint related to these products, consumers should contact us via email: MV-SouthAfrica@bauschhealth.com.

Consumers should contact their eye care professional for further care and instruction related to an adverse event.

Retailers, pharmacies, eye care professionals, distributors and wholesalers who have purchased products directly from Bausch + Lomb are asked to contact Sedgwick at 080 099 4885 to arrange for pickup of the identified product and for Return Material Authorization instructions. If the products were not purchased directly from Bausch + Lomb, customers are asked to contact their re-seller to return the product and discuss exchange or refund options.

Recalled Product Details*	
Expiration Dates: May 2021 – February 2024	
	Biotrue® Multi-purpose Solution 60 ml Biotrue® Multi-purpose Solution 300 ml Biotrue® Multi-purpose Solution Flight Pack [2 x 60 ml] Biotrue® Multi-purpose Solution 300 ml (1 x 2)
	Boston® Advance Cleaner 30 ml

Recalled Product Details*	
	<p>Boston® Advance Conditioning Solution 120 ml</p>
	<p>Boston® Simplus Multi-Action Solution 120 ml</p>
	<p>EasySept® Peroxide Solution 120 ml EasySept® Peroxide Solution 360 ml</p>
	<p>Lens Lubricant® 15 ml</p>

Recalled Product Details*	
	<p>ReNu® MultiPlus Solution 60 ml ReNu® MultiPlus Solution 120 ml ReNu® MultiPlus Solution 240 ml ReNu® MultiPlus Solution 360 ml ReNu® MultiPlus Solution Flight Pack [2 x 60 ml] ReNu® MultiPlus Solution 240 ml (1 x 2) ReNu® MultiPlus Solution 240 ml (1 x 3) ReNu® MultiPlus Solution 360 ml (1 x 2) ReNu® MultiPlus Solution 360 ml + 240 ml</p>
	<p>ReNu® Multi-Purpose Solution 60 ml ReNu® Multi-Purpose Solution 120 ml ReNu® Multi-Purpose Solution 240 ml ReNu® Multi-Purpose Solution 360 ml ReNu® Multi-Purpose Solution Flight Pack [2 x 60 ml] ReNu® Multi-Purpose Solution 240 ml (1 x 2) ReNu® Multi-Purpose Solution 240 ml (1 x 3) ReNu® Multi-Purpose Solution 360 ml (1 x 2) ReNu® Multi-Purpose Solution 360 ml + 240 ml</p>
	<p>Saline Plus® Solution 360 ml</p>

**Images in the Recalled Product Details section are examples only. The products or packaging of these products may differ depending on the region/country.*

About Bausch + Lomb

Bausch + Lomb, a leading global eye health business of Bausch Health Companies Inc., is solely focused on helping people see better to live better. Its core businesses include over-the-counter products, dietary supplements, eye care products, ophthalmic pharmaceuticals, contact lenses, lens care products, ophthalmic surgical devices and instruments. Bausch + Lomb develops, manufactures and markets one of the most comprehensive product portfolios in the industry, which is available in approximately 100 countries. For more information, visit www.bausch.com.



We greatly appreciate your understanding and prompt assistance and apologize for any inconvenience this may cause.

Sincerely,

Lizé Theunissen
Authorised Representative

Shirona Naidoo
Quality and Vigilance Specialist

*®/TM are trademarks of Bausch & Lomb Incorporated or its affiliates.
All other product/brand names and/or logos are trademarks of the respective owners.
© 2021 Bausch & Lomb Incorporated or its affiliates.*