

Family Care, Major, and Rugby – Recall of Eye Solutions

- On September 7, 2016, the <u>FDA announced</u> a recall of some lots of <u>Family Care eye wash</u>, <u>Rugby eye irrigating solution</u> and <u>Major eye wash</u>, due to microbial contamination. United Exchange Corp. is a primary source vendor of the Rugby and Major eye irrigation/eye wash solutions.
 - Eye wash/eye irrigation consist of a purified water solution and is used to flush the eye to relieve irritation, stinging, or itching by removing foreign material such as air pollutants or chlorinated water.
- United Exchange learned of the potential issue through the receipt of a product complaint. No illnesses have been reported to date.
- These products were distributed nationwide to wholesale and retail facilities including hospitals and pharmacies. The impacted lots are listed below.

Product Description	NDC #	Lot # (Expiration Date)
Rugby Eye Irrigating Solution 4 oz (118mL) bottle	0536-1083-97	G15908 (10/2018); G15909 (11/2018); G16904 (1/2019); G16908 (2/2019); G16912 (3/2019); G16913 (3/2019)
Major Eye Wash 4 oz (118mL) bottle	0904-6491-20	G15905 (10/2018); G15906 (10/2018); G15907 (10/2018); G15910 (11/2018); G15911 (11/2018); G15912 (11/2018); G16901 (1/2019); G16902 (1/2019); G16903 (1/2019); G16905 (2/2019); G16906 (2/2019); G16907 (2/2019); G16910 (3/2019); G16911 (3/2019)
Family Care Eye Wash 4 oz (118mL) bottle (distributed by United Exchange)	65923-582-04	G15901 (7/31/2018); G15902 (7/31/2018); G15903 (7/31/2018); G15904 (7/31/2018); G16909 (5/30/2019)

- Use of a contaminated product could be calamitous for any population since there is a reasonable probability of a potentially sight-threatening eye infection.
- As part of a commitment to patient safety, Rugby and Major are working with United Exchange to notify customers who may be in possession of either eye irrigating solution or eye wash.

- United Exchange is notifying its distributors and customers by recall letter and is arranging for return of all recalled products. Consumers, pharmacies, and healthcare facilities that have product which is being recalled should stop using and dispensing them immediately.
- Questions regarding the recalled Rugby or Major product should be directed to Rugby's Customer Support Department at 1-800-645-2158.
- Questions regarding the recalled Family Care product should be directed to the United Exchange Customer Service Department at 1-800-814-8028.
- Patients with any additional questions regarding these products should be directed to a healthcare provider.

Action Plan

- No utilization was identified thus patient and provider mailings will not be conducted.
- Information regarding the eye irrigation/eye wash recall will be posted on the optumrx.com portals.



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