RUGBY EYE WASH- water, purified liquid
Rugby Laboratories

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active ingredients

Purified water (99.05%)

Purpose

Eyewash

Uses

washes the eye to help relieve
- irritation
- discomfort
- burning
- stinging
- itching

by removing
- loose foreign material
- air pollutants (smog or pollen)
- chlorinated water

Warnings
For external use only

Do not use
- if you have open wounds in or near the eyes, and get medical help right away
- if solution changes color or becomes cloudy

When using this product
- remove contact lenses before using
- do not touch the tip of container to any surface to avoid contamination
- replace cap after each use

Stop use and ask a doctor if
• you experience eye pain, changes in vision, continued redness or irritation of the eye
• condition worsens or persists

Keep out of reach of children
If swallowed, get medical help or contact a Poison Control Center right away

Directions

For use with nozzle applicator
- flush the affected eye(s) as needed
- control the rate of flow of solution by pressure on the bottle
- do not touch dropper tip to eye

When using an eye cup
- rinse the cup with Eye Wash Solution immediately before each use

- avoid contamination of the rim and inside surfaces of the cup
- fill the cup half full with Eye Wash Solution and apply the cup to the affected eye(s), pressing tightly to prevent spillage
- tilt the head backward. Open eyelids wide and rotate eyeball to thoroughly wash the eye
- rinse cup with clean water after each use
- replace cap after use

Other information

- Store at 15°-25°C (59°-77°F)
- keep tightly closed
- does not contain thimerosal
- enclosed eyecup is sterile if packaging is intact
- use before expiration date marked on the carton or bottle

Inactive ingredients

boric acid, sodium borate and sodium chloride. PRESERVATIVE ADDED: BENZALKONIUM CHLORIDE (0.01%)

NIOC

DO NOT USE IF BLUE WAVE IMPRINTED NECKBAND IS NOT INTACT.

Drug Facts (continued)

When using an eye cup
- rinse the cup with Eye Wash Solution immediately before each use
- avoid contamination of the rim and inside surfaces of the cup
- fill the cup half full with Eye Wash Solution and apply the cup to the affected eye(s), pressing tightly to prevent spillage
- tilt the head backward. Open eyelids wide and rotate eyeball to thoroughly wash the eye
- rinse cup with clean water after each use
- replace cap after use

Other information
- store at 15°-25°C (59°-77°F)
- keep tightly closed
- does not contain thimerosal
- enclosed eyecup is sterile if packaging is intact
- use before expiration date marked on the carton or bottle

Inactive ingredients
boric acid, sodium borate and sodium chloride. PRESERVATIVE ADDED: benzalkonium chloride (0.01%)

Questions or comments?
Toll Free Product Information or to Report a Serious Side Effect Associated with use of this product Call: **1-800-645-2158**

FOR USE IN THE EYES ONLY

Distributed by: Rugby Laboratories
17177 N Laurel Park Drive, Suite 233
Livonia, MI 48152
www.rugbylaboratories.com

Rev. 12/18 R-93 Re-order No: 370680

Rugby NDC 0536-1224-97

FOR DAILY OR EMERGENCY EYE CLEANSING

Eye Wash

Eye Irrigating Solution

FOR EMERGENCY USE:
A sterile solution to flush irritants from eyes.

FOR EVERYDAY USE:
- Cleanses and refreshes your eyes.
- Helps relieve burning, stinging, irritated eyes.
- Removes pollen or smog.
- Removes chlorinated water.

Sterile Eye Cup Enclosed

Rugby NDC 0536-1224-97

FOR DAILY OR EMERGENCY EYE CLEANSING

Eye Wash

Eye Irrigating Solution

- Cleanses
- Refreshes
- Soothes
- Sterile Eye Cup Included

STERILE
4 FL OZ (118 mL)

CEWAS0401R00
3 05361 22497 4
LOT
EXP

Drug Facts

Active Ingredient	Purpose
Purified water (99.05%)	Eyewash

Uses
washes the eye to help relieve
- irritation
- discomfort
- burning
- stinging
- itching

by removing
- loose foreign material
- air pollutants (smog or pollen)
- chlorinated water

Warnings
For external use only

Do not use
- if you have open wounds in or near the eyes, and get medical help right away
- if solution changes color or becomes cloudy

When using this product
- remove contact lenses before using
- do not touch tip of container to any surface to avoid contamination
- replace cap after use

Stop use and ask a doctor if
- you experience eye pain, changes in vision, continued redness or irritation of the eye
- condition worsens or persists

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
For use with nozzle applicator.
- flush the affected eye(s) as needed
- control the rate of flow of solution by pressure on the bottle
- do not touch dropper tip to eye

▶

NIOC

RUGBY EYE WASH
water, purified liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0536-1224
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	99.05 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BORIC ACID (UNII: R57ZHV85D4)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0536-1224-97	1 in 1 BOX	02/22/2019	
1		118 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	02/22/2019	

Labeler - Rugby Laboratories (079246066)

Registrant - KC Pharmaceuticals, Inc. (174450460)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		114406598	manufacture(0536-1224)

Establishment

Name	Address	ID/FEI	Business Operations
KC Pharmaceuticals		174450460	pack(0536-1224) , label(0536-1224)

Revised: 4/2019 Rugby Laboratories