LEADER EYE WASH- purified water liquid
Cardinal Health

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 Ingredient

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 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 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 affected eye(s), pressing tightly to prevent spillage
- tilt the head backward. Open eyelids wide and rotate eyeballs 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

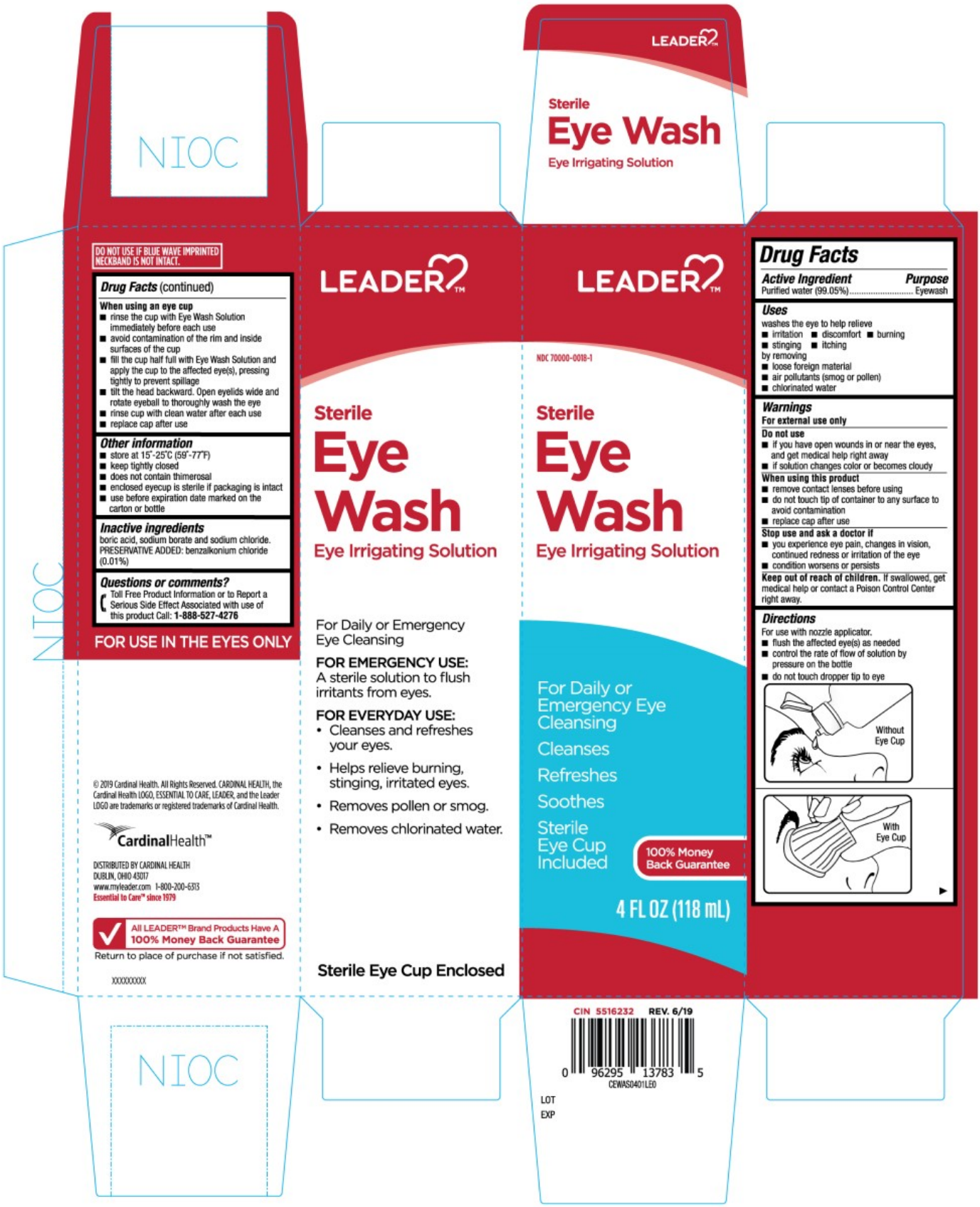
boric acid, sodium borate and sodium chloride.

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: 1-888-527-4276

Leader Eye Wash



LEADER EYE WASH

purified water liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0018
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)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70000-0018-1	1 in 1 BOX	07/09/2019	
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	07/09/2019	

Labeler - Cardinal Health (097537435)

Registrant - KC Pharmaceuticals, Inc. (174450460)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorperated		114406598	manufacture(70000-0018)

Establishment

Name	Address	ID/FEI	Business Operations
KC Pharmaceuticals, Inc.		174450460	pack(70000-0018) , label(70000-0018)