PHYSICIANS CARE EYE WASH STERILE BUFFERED ISOTONIC- water solution Acme United Corporation

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.

Physicians Care® Eye Wash Sterile Buffered Isotonic Solution

Drug Facts

Active Ingredient

Purified water 98%

Purpose

Eyewash

Indications

For flushing the eyes to help relieve irritation, discomfort, burning, stinging, or itching by removing loose foreign material and air pollutants (smog or pollen).

Warnings

For external use only

- To avoid contamination, do not touch tip of bottle to any surface
- Do not reuse
- Discard bottle after use

Do not use

- If solution changes color or becomes cloudy
- With contact lenses
- If bottle is open or seal is broken

Stop use and consult a doctor if you experience

- Eye pain
- Changes in vision
- Continued redness or irritation of the eye or if the condition worsens or persists

Obtain immediate medical treatment for all open wounds in or near the eyes.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- To pour hold bottle securely, twist off top to remove
- Control rate of flow by pressure on the bottle
- Flush the affected eye(s) as needed
- Do not touch bottle tip to eye
- If necessary, continue flushing with emerengcy eyewash or shower.

Inactive Ingredients

Benzalkonium chloride, edetate disodium dihydrate, sodium chloride, sodium phosphate dibasic heptahydrate, sodium phosphate monobasic monohydrate.

Questions or Comments?

Call Toll Free: 800-835-2263

Store at 59 - 86°F (15 - 30°C)

PRINCIPAL DISPLAY PANEL - 946 ml Bottle Label

Physicians $CARE_{\mathbb{R}}$

NDC 0924-0167-32

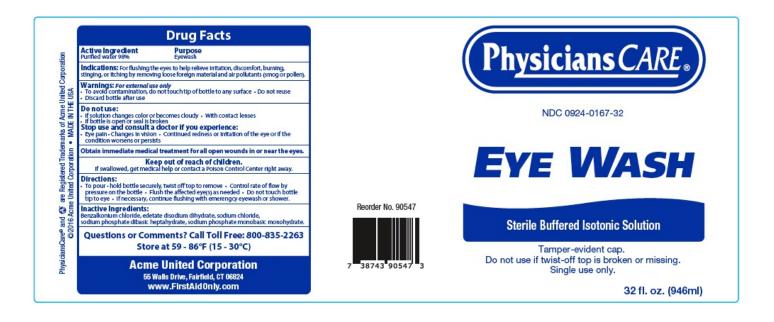
EYE WASH

Sterile Buffered Isotonic Solution

Tamper-evident cap.

Do not use if twist-off top is broken or missing. Single use only.

32 fl. oz. (946ml)



PHYSICIANS CARE EYE WASH STERILE BUFFERED ISOTONIC water solution Product Information Product Type HUMAN OTC DRUG Route of Administration OPHTHALMIC Active Ingredient/Active Moiety

	Ingredient Name	Basis of Strength	Strength
l	Water (UNII: 059QF0KO0R) (Water - UNII:059QF0KO0R)	Water	0.98 mL in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
Benzalkonium chloride (UNII: F5UM2KM3W7)		
Edetate disodium (UNII: 7FLD91C86K)		
Sodium chloride (UNII: 451W47IQ8X)		
Sodium phosphate, Dibasic, Heptahydrate (UNII: 70WT22SF4B)		
Sodium Phosphate, Monobasic, Monohydrate (UNII: 593YOG76RN)		

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:0924-0167- 32	12 in 1 BOX, UNIT-DOSE	02/29/2016			
1		946 mL in 1 BOTTLE, UNIT-DOSE; Type 0: Not a Combination Product				
2	NDC:0924-0167- 16	12 in 1 BOX, UNIT-DOSE	02/29/2016			
2		480 mL in 1 BOTTLE, UNIT-DOSE; Type 0: Not a Combination Product				
3	NDC:0924-0167- 01	144 in 1 BOX, UNIT-DOSE	02/29/2016			
3		30 mL in 1 BOTTLE, UNIT-DOSE; 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	02/29/2016			

Labeler - Acme United Corporation (001180207)

Registrant - Horizon Pharmaceuticals, Inc. (960418825)

Establishment				
Name	Address	ID/FEI	Business Operations	
Horizon Pharmaceuticals, Inc.		960418825	MANUFACTURE(0924-0167), STERILIZE(0924-0167), LABEL(0924-0167), PACK(0924-0167), ANALYSIS(0924-0167)	

Revised: 11/2019 Acme United Corporation