

**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.*

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**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 emergency 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®

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)**

<small>PhysiciansCare® and © are Registered Trademarks of Acme United Corporation ©2016 Acme United Corporation • MADE IN THE USA</small>	<b>Drug Facts</b>	 NDC 0924-0167-32  <b>EYE WASH</b>  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)	
	<b>Active Ingredient</b> Purified water 98%		<b>Purpose</b> Eyewash
	<b>Indications:</b> For flushing the eyes to help relieve irritation, discomfort, burning, stinging, or itching by removing loose foreign material and air pollutants (smog or pollen).		
	<b>Warnings: For external use only</b> • To avoid contamination, do not touch tip of bottle to any surface • Do not reuse • Discard bottle after use		
	<b>Do not use:</b> • If solution changes color or becomes cloudy • With contact lenses • If bottle is open or seal is broken		
	<b>Stop use and consult a doctor if you experience:</b> • Eye pain • Changes in vision • Continued redness or irritation of the eye or if the condition worsens or persists		
	<b>Obtain immediate medical treatment for all open wounds in or near the eyes.</b> <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.		
	<b>Directions:</b> • 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 emergency eyewash or shower.		
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	<b>Questions or Comments? Call Toll Free: 800-835-2263</b> <b>Store at 59 - 86°F (15 - 30°C)</b>		
<b>Acme United Corporation</b> 55 Walls Drive, Fairfield, CT 06824 www.FirstAidOnly.com			
Reorder No. 90547  7 38743 90547 3			

## PHYSICIANS CARE EYE WASH STERILE BUFFERED ISOTONIC

water solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0924-0167
<b>Route of Administration</b>	OPHTHALMIC		

**Active Ingredient/Active Moiety**

Ingredient Name		Basis of Strength	Strength	
Water (UNII: 059QF0KO0R) (Water - UNII:059QF0KO0R)		Water	0.98 mL in 1 mL	
<b>Inactive Ingredients</b>				
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)				
<b>Packaging</b>				
#	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		
<b>Marketing Information</b>				
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)