FAD FIRST AID DIRECT EYEWASH- purified water solution XPECT FIRST AID BUFFERED EYEWASH- purified water solution EYEWASH FLUSHING SOLUTION- purified water solution XPECT FIRST AID BUFFERED EYE AND SKIN- purified water solution FAD FIRST AID DIRECT BUFFERED EYE AND SKIN- purified water solution Cintas 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.

Drug Facts

Active ingredient

Purified water 98.577% w/v

Purpose

eye wash

Uses

• For flushing the eye to remove loose foreign material or air pollutants (smog or pollen)

Warnings

For external use only

Do not use

If solution changes color or becomes cloudy

When using this product

- Remove contact lenses before using
- Avoid contamination, do not touch tip of container to any surface
- Do not reuse, once open, discard

Stop use and ask a doctor if

- You experience eye pain
- Changes in vision occur
- 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

• Flush the affected eye as needed, controlling the rate of flow of solution by pressure on the bottle

Other information

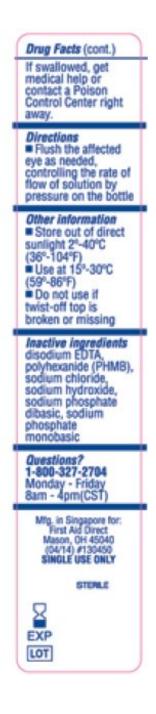
- Store out of direct sunlight 2°-40°C (36°-104°F)
- Use at 15°-30°C (59°-86°F)
- Do not use if twist-off top is broken or missing

Inactive ingredients

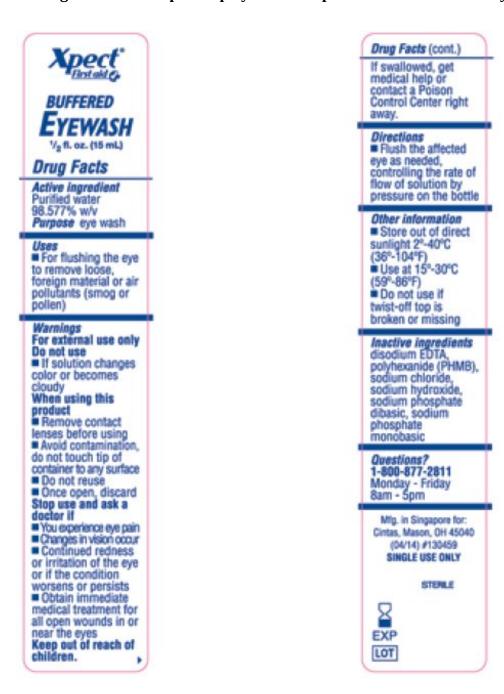
disodium EDTA, polyhexanide (PHMB), sodium chloride, sodium hydroxide, sodium phosphate dibasic, sodium phosphate monobasic

Package /Label Principal Display Panel – fad first aid direct Eyewash





Package/Label Principal Display Panel - Xpect First aid Buffered Eyewash



Package/Label Principal Display Panel – Eyewash Flushing Solution



Evewash

FLUSHING SOLUTION

Sterile Isotonic Buffered Flushing Solution

Single Use Only

CAUTION: Tamper-evident cap.

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

4 fl. oz. (118 mL)

Package/Label Principal Display Panel – Xpect First aid Buffered Eye & Skin



BUFFERED Eye & Skin

Sterile Isotonic Buffered Flushing Solution

Single use only

CAUTION: Tamper-evident cap.

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

4 fl. oz. (118 mL)

Xpect[®] First aid

Package/Label Principal Display Panel – fad first aid direct Buffered Eye & Skin



BUFFERED Eye & Skin

Sterile Isotonic Buffered Flushing Solution

SINGLE USE ONLY

CAUTION: Tamper-evident cap. Do not use if twist-off top is broken or missing.

8 fl. oz. (236 mL)

fad first aid direct®

Package/Label Principal Display Panel – fad first aid direct Buffered Eye & Skin



BUFFERED Eye & Skin

Sterile Isotonic Buffered Flushing Solution

SINGLE USE ONLY

CAUTION: Tamper-evident cap. Do not use if twist-off top is broken or missing.

16 fl. oz. (474 mL)

fad first aid direct®

Product Information Product Type HUMAN OTC DRUG | Item Code (Source) | NDC:42961-090 | OPERITAL MICHER PROJECTION, TODICAL

Active Ingredient/Active Moiety	Active	Ingredien	t/Active	Moiety
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ı	reduce ingredient reduces			
l	Ingredient Name	Basis of Strength	Strength	
l	WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	985.77 g in 1000 mL	

Inactive Ingredients	
Ingredient Name	Strength
POLIHEXANIDE (UNII: 322U039GMF)	
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)	
SODIUM HYDRO XIDE (UNII: 55X04QC32I)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SO DIUM PHO SPHATE, DIBASIC, DO DECAHYDRATE (UNII: E1W4N241FO)	
SO DIUM PHO SPHATE, MO NO BASIC, DIHYDRATE (UNII: 5QWK665956)	

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:42961-090-01	15 mL in 1 VIAL, SINGLE-USE	07/15/2014	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part349	07/15/2014		

XPECT FIRST AID BUFFERED EYEWASH

purified water solution

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42961- 091		
Route of Administration	OPHTHALMIC, IRRIGATION, TOPICAL, CUTANEOUS				

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	985.77 g in 1000 mL		

	Inactive Ingredients	
ı	Ingredient Name	Strength
ı	POLIHEXANIDE (UNII: 322U039GMF)	

EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
SODIUM HYDRO XIDE (UNII: 55X04QC32I)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SO DIUM PHO SPHATE, DIBASIC, DO DECAHYDRATE (UNII: E1W4N241FO)	
SO DIUM PHO SPHATE, MO NO BASIC, DIHYDRATE (UNII: 5QWK665956)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:42961-091-02	5 in 1 BOX	07/15/2014		
1	NDC:42961-091-01	15 mL in 1 VIAL, SINGLE-USE			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part349	07/15/2014		

EYEWASH FLUSHING SOLUTION

purified water solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42961- 092	
Route of Administration	OPHTHALMIC, IRRIGATION, TOPICAL, CUTANEOUS			

l	Active Ingredient/Active Moiety				
l	Ingredient Name	Basis of Strength	Strength		
ı	WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	985.77 g in 1000 mL		

Inactive Ingredients	
Ingredient Name	Strength
POLIHEXANIDE (UNII: 322U039GMF)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
SO DIUM HYDRO XIDE (UNII: 55X0 4QC32I)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SO DIUM PHO SPHATE, DIBASIC, DO DECAHYDRATE (UNII: E1W4N241FO)	
SO DIUM PHO SPHATE, MO NO BASIC, DIHYDRATE (UNII: 5QWK665956)	

Pac	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 ND	OC:42961-092-01	118 mL in 1 BOTTLE, PLASTIC	07/15/2014			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part349	07/15/2014			

XPECT FIRST AID BUFFERED EYE AND SKIN

purified water solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42961- 093	
Route of Administration	OPHTHALMIC, IRRIGATION, TOPICAL, CUTANEOUS			

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	985.77 g in 1000 mL			

Inactive Ingredients				
Ingredient Name	Strength			
POLIHEXANIDE (UNII: 322U039GMF)				
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)				
SODIUM HYDRO XIDE (UNII: 55X04QC32I)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SO DIUM PHO SPHATE, DIBASIC, DO DECAHYDRATE (UNII: E1W4N241FO)				
SO DIUM PHO SPHATE, MO NO BASIC, DIHYDRATE (UNII: 5QWK665956)				

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:42961-093-01	118 mL in 1 BOTTLE, PLASTIC	07/15/2014			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part349	07/15/2014			

FAD FIRST AID DIRECT BUFFERED EYE AND SKIN

purified water solution

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Proa	liict	Infort	nation

NDC: 420C

Product Type	HUMAN OTC DRUG	(Source)	NDC:42901- 094
Route of Administration	OPHTHALMIC, IRRIGATION, TOPICAL, CUTANEOUS		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	985.77 g in 1000 mL		

Inactive Ingredients				
Ingredient Name	Strength			
POLIHEXANIDE (UNII: 322U039GMF)				
EDETATE DISO DIUM (UNII: 7FLD91C86K)				
SO DIUM HYDRO XIDE (UNII: 55X0 4QC32I)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SO DIUM PHO SPHATE, DIBASIC, DO DECAHYDRATE (UNII: E1W4N241FO)				
SO DIUM PHO SPHATE, MO NO BASIC, DIHYDRATE (UNII: 5QWK665956)				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:42961-094-01	236 mL in 1 BOTTLE, PLASTIC	07/15/2014			
2	NDC:42961-094-02	474 mL in 1 BOTTLE, PLASTIC	07/15/2014			

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part349	07/15/2014				

Labeler - Cintas Corporation (056481716)

Revised: 7/2014 Cintas Corporation