

SPERIAN EYESALINE EYEWASH - water liquid
Sperian Eye & Face Protection Inc

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.

Sperian Eyesaline Eyewash

Active ingredient

Water 99.8%

Purpose

Emergency eyewash

Uses

- for flushing or irrigating the eye to reduce chances of severe injury caused by acid, alkali, or particulate contamination.

Warnings

For external use only

Do not use

- if solution changes color or gets cloudy
- with contact lenses
- if twist-off top is broken or missing
- in open wounds in or near the eyes

When using this product

- avoid contamination, do not touch tip of container to any surface

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Stop use and consult a doctor if you have

- changes in vision
- eye pain
- continued redness or irritation of the eye, or if the condition worsens or persists

Keep out of reach of children.

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

Directions

- remove contacts before using
- twist top to remove
- flush the affected eye as needed, controlling the rate of flow of the solution by pressure on the bottle
- if necessary, continue flushing with emergency eyewash or shower

- do not reuse
- once opened, discard
- obtain medical treatment

Other information

- store at room temperature, 15° to 30° C (59° to 86° F)
- do not freeze

Inactive ingredients

sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic

Questions?

1-800 - 430-5490

Sperian Eye and Face Protection, Inc.
 (a Honeywell Company)
 825 East Highway 151
 Platteville, WI 53818 USA

Principal Display Panel

<p>TAMPER-EVIDENT CAP. DO NOT USE IF TWIST-OFF TOP IS BROKEN OR MISSING.</p>	
 <p>Sterile Isotonic Solution 8 fl. oz. (237 ml.)</p>	<p>Drug Facts (for USA only)</p> <p>Active ingredient: Sterile water 99.8% Purpose: Emergency eyewash</p> <p>Uses For flushing or irrigating the eye to reduce chances of severe injury caused by acid, alkali, or particulate contamination</p> <p>Warnings: Do not use • if solution changes color or gets cloudy • with contact lenses • in open wounds in or near the eyes</p> <p>For external use only</p> <p>When using this product • avoid contamination, do not touch tip of container to any surface</p> <p>Stop use and consult a doctor if you have • changes in vision • eye pain • continued redness or irritation of the eye, or if the condition worsens or persists</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away →</p>
	<p>Drug Facts (continued)</p> <p>Directions • remove contacts before using • twist top to remove • flush the affected area as needed, controlling the rate of flow of the solution by pressure on the bottle • if necessary, continue flushing with emergency eyewash or shower • do not reuse • once opened, discard • obtain medical treatment</p> <p>Other information • store at room temperature, 15° to 30°C (59° to 86°F) • do not freeze</p> <p>Inactive ingredients sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic</p> <p>Questions? 1-800-430-5490 Sperian Eye & Face Protection, Inc. (a Honeywell Company) 825 East Highway 151 Platteville, WI 53818 USA</p>
<p>LABEL #92-004611 Rev F REORDER #92-000446-0000 space for lot code and supplier part</p>	

← FINAL UNWIND

SPERIAN EYESALINE EYEWASH

water liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64809-101
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	99.8 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
SODIUM PHOSPHATE, DIBASIC ANHYDROUS (UNII: 22ADO53M6F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64809-101-12	30 mL in 1 BOTTLE, PLASTIC		
2	NDC:64809-101-13	118 mL in 1 BOTTLE, PLASTIC		
3	NDC:64809-101-14	237 mL in 1 BOTTLE, PLASTIC		
4	NDC:64809-101-15	473 mL in 1 BOTTLE, PLASTIC		
5	NDC:64809-101-16	946 mL in 1 BOTTLE, PLASTIC		
6	NDC:64809-101-21	15 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	09/07/2011	

Labeler - Sperian Eye & Face Protection Inc (013435034)

Establishment

Name	Address	ID/FEI	Business Operations
Sperian Eye & Face Protection Inc		013435034	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Medex Cardio Pulmonary dba Smiths Medical		835634168	manufacture

