

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

Drug Facts

Active ingredient

Sterile water 99%

Purpose

Eyewash

Uses

For flushing the eye to remove loose foreign material, air pollutants, or chlorinated water.

Warnings

For external use only

Obtain immediate medical treatment for all open wounds in or near the eyes. To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard.

Do not use

- if solution changes color or becomes cloudy
- if you have open wounds in or near the eyes. Get medical help right away.

When using this product

- do not touch tip of container to any surface to avoid contamination
- remove contact lenses before using
- replace cap after use

Stop use and consult a doctor if you have

- 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 a Poison Control Center right away.

Directions

- flush the affected eye as needed
- control the rate of flow of the solution by pressure on the bottle
- if necessary, continue flushing with emergency eyewash or shower

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 E Highway 151
Platteville, WI 53818

Honeywell

eyesaline EYEWASH

Sterile Isotonic Solution

1 fl. oz. (30 ml)

| | | | |
|------------|---------------------------|---|--|
| Hinge Area | Lot number (do not print) | <p>Drug Facts</p> <p>Active ingredient Sterile water 99% Eyewash</p> <p>Purpose Eyewash</p> <p>Uses For flushing the eye to remove loose foreign material, air pollutants, or chlorinated water.</p> <p>Warnings For external use only Obtain immediate medical treatment for all open wounds in or near the eyes. To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard.</p> <p>Do not use • if solution changes color or becomes cloudy • if you have open wounds in or near the eyes. Get medical help right away.</p> <p>When using this product • do not touch tip of container to any surface to avoid contamination • remove contact lenses before using • replace cap after use</p> <p>Stop use and consult a doctor if you have • you experience eye pain, changes in vision, continued redness or irritation of the eye</p> | <p>Drug Facts (continued)</p> <p>• 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>Directions • flush the affected area as needed • control the rate of flow of solution by pressure on the bottle • if necessary, continue flushing with emergency eyewash or shower</p> <p>Inactive ingredients sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic</p> <p>Questions? Call 1-800-430-5490</p> <p>Sperian Eye and Face Protection, Inc. (a Honeywell company) 825 E. Highway 151, Platteville, WI 53818</p> <p>eyesaline Honeywell</p> <p>EYEWASH Sterile Isotonic Solution</p> <p>1 fl. oz. (30 ml)</p> <p>PEEL PELAR PELEP</p> |
| | | <p>LABEL #82-004513 Rev. H REORDER #82-000451-0000</p> | |

SPERIAN EYESALINE EYEWASH

water liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:64809-102 |
| Route of Administration | OPHTHALMIC | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R) | WATER | 99 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
| | | | | |

| | | | | |
|---|------------------|---|------------|--|
| 1 | NDC:64809-102-12 | 30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/18/2018 | |
|---|------------------|---|------------|--|

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part349 | 06/18/2018 | |

Labeler - Sperian Eye & Face Protection Inc (013435034)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------------|---------|-----------|------------------------|
| Sperian Eye & Face Protection Inc | | 013435034 | manufacture(64809-102) |

Revised: 6/2018

Sperian Eye & Face Protection Inc