

SALINAAX EYE WASH- water rinse
Aaxis Pharmaceuticals Inc Dba Aaxis Pacific

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.

Active Ingredient

Purified water USP 98.6%

Purpose

Eye Wash

Uses:

For irrigating the eye to help relieve irritation by removing loose foreign material, air pollutants, and chlorinated water.

Warnings

Do not use

- If solution changes color or becomes cloudy
- If snap off top is broken or missing

When using this product

- Remove contact lenses before use
- Do not touch the tip of container to any surface to avoid contamination

Stop use and consult a doctor

- If you experience eye pain, change in vision, continued redness or irritation of the eye
- If condition worsens or persists
- If there are open wounds in or near the eye

Keep out of reach of children

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

Directions

- Twist snap-off top to open
- Flush affected eye as needed, controlling the rate of flow of solution by pressure on the container
- DO not reuse
- Discard container after use

Storage

Store out of direct sunlight between 59⁰F and 86⁰F (15⁰C and 30⁰C)

Inactive Ingredients:

PHMB, Potassium phosphate monobasic, sodium chloride USP, sodium hydroxide.

Questions

Tel: 1-424-263-5294

Principal Display Panel

NDC numbers - 68276-006-01, 02, 03, 04, 05

Salinaax

EYE WASH

Sterile Buffered Isotonic Solution with Preservative

For emergency eye cleaning and First Aid use.

Cleans, refreshes, soothes

TAMPER-EVIDENT CAP

DO NOT USE IF SNAP-OFF TOP IS BROKEN OR MISSING

STERILEA

Sterile using aseptic processing technique

68786-006-05..... 0.5 fl.oz (15mL)

68786-006-01..... 5.0 fl.oz (148mL)

68786-006-02..... 8.0 fl.oz (236mL)

68786-006-03..... 16 fl.oz (472mL)

68786-006-04..... 32 fl.oz (944mL)

 Salinaax[®] EYE WASH	Drug Facts
	Active ingredients: Purified water USP 98.6%..... Purpose: Eye Wash
Uses: For irrigating the eye to help relieve irritation by removing loose foreign material, air pollutants and chlorinated water	Warnings: Do not use: • If solution changes color or becomes cloudy • If snap off top is broken or missing
When using this product: • Remove contact lenses before use • Do not touch tip of container to any surface to avoid contamination	Stop use and consult a doctor: • If you experience eye pain, changes in vision, continued redness or irritation of the eye • If condition worsens or persists • If there are open wounds in or near the eye
Keep out of reach of children: If swallowed, get medical help or contact a Poison Control Center right away	Directions: • Twist snap-off top to open • Flush affected eye as needed, controlling the rate of flow of solution by pressure on the container • Do not reuse • Discard container after use
Storage: • Store out of direct sunlight between 59°F and 86°F (15°C and 30°C)	Inactive ingredients: PHMB, Potassium phosphate monobasic, sodium chloride, sodium hydroxide

Questions: Tel: 1-424-263-5294

Code: 13217031

Manufactured for: Axis Pharmaceuticals Inc.
1835 262nd Street
Lomita, CA 90717
www.salinaaxeyewash.com

LOT

STERILEA
Sterile using aseptic processing techniques

5fl.oz (148ml)
NDC68276-006-01

TAMPER-EVIDENT CAP. DO NOT USE IF SNAP-OFF TOP IS BROKEN OR MISSING

Compliance: ANSI/SEA Z358.1-2009
21 CFR Part 349
(As personal Eye Wash only)

For emergency eye cleansing and First Aid use
Cleans, refreshes, soothes

Sterile Buffered Isotonic Solution with Preservative



SALINAAX EYE WASH

water rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68276-006	
Route of Administration	OPHTHALMIC			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
Water (UNII: 059QF0KO0R) (Water - UNII:059QF0KO0R)		Water	98.6 mL in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
Potassium phosphate, monobasic (UNII: 4J9FJ0HL51)				
Sodium chloride (UNII: 451W47IQ8X)				
Sodium hydroxide (UNII: 55X04QC32I)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68276-006-01	148 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2010	
2	NDC:68276-006-02	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2010	
3	NDC:68276-006-03	472 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2010	
4	NDC:68276-006-04	944 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2010	
5	NDC:68276-006-05	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2010	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part349	06/18/2010		

Labeler - Aaxis Pharmaceuticals Inc DbA Aaxis Pacific (049082677)

Registrant - Opto-Pharm Pte Ltd (595239682)