

SALINAAX EYE WASH AND SKIN FLUSH- water rinse

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 Ingredients :

Purified water USP 98.6%

Purpose:

Eye wash and skin flush

Uses: For irrigating the eyes to remove loose foreign material, air pollutants, chlorinated water and for flushing the skin.

Warnings: For external use only. To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard, do not transfer to other bottle containers. If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists, consult a doctor, obtain immediate medical treatment for all open wounds in or near the eyes. If solution changes color or becomes cloudy, do not use.

Do Not Use:For injection, with contact lenses, If eye is lacerated or object is embedded, If twist top is broken or missing.

If solution changes color or becomes cloud, do not use.

Keep out of reach of children.

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

Directions: Twist top to open, flush the affected eye as needed, controlling the rate of flow of solution by pressure on the bottle, discard bottle after use.

Other Information:

Store out of direct sunlight between 15 degrees C and 30 degrees C (59 degrees F - 86 degrees F)

Inactive Ingredients:

Potassium phosphate monobasic, sodium chloride USP, sodium hydroxide.

Salinaax®

TAMPER-EVIDENT CA DO NOT USE IF TWIST-OFF OP IS BROKEN OR MISSING

PRESERVATIVE FREE

eye wash & skin flush

SINGLE USE ONLY

Sterile Buffered Isotonic Solution

5fl.oz (148ml)

COMPLIANCE: ANSI/ISEA Z358.1-2009 (AS PERSONAL EYE WASH ONLY)

STERILE A Sterile using aseptic processing techniques

AXIS Excelling In Healthcare Solutions

Drug Facts

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NDC IN # XXXXXXXXXXXXXXXX
Code: 13217021
93253341015638

Manufactured for
AXIS PACIFIC
24-32 Forge St Blacktown
NSW 2148 Australia
www.axispacific.com.au
Made in Singapore

LOT

Salinaax
 Tamper-evident ca do not use if twist-off or is broken or missing
 Preservative free
 Eye Wash and Skin Flush
 Single Use Only
 Sterile Buffered Isotonic Solution
 5fl.oz (148ml)
 Compliance: Ansi/isea
 (As personal eye wash only)
 AAXIS Excelling in healthcare solutions

SALINAAX EYE WASH AND SKIN FLUSH

water rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68276-005
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: 451W471Q8X)	

Sodium hydroxide (UNII: 55X04QC32I)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68276-005-01	148 mL in 1 BOTTLE		
2	NDC:68276-005-02	236 mL in 1 BOTTLE		
3	NDC:68276-005-03	472 mL in 1 BOTTLE		
4	NDC:68276-005-04	944 mL in 1 BOTTLE		
5	NDC:68276-005-05	15 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	03/11/2011	

Labeler - Aaxis Pacific (751370305)

Establishment

Name	Address	ID/FEI	Business Operations
Opto Pharm Pte Ltd		595239682	manufacture

Revised: 3/2011

Aaxis Pacific