

AEROWASH EYEWASH AND SKIN-RINSE- purified water solution

Aero Healthcare

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.

AEROWASH EYEWASH

Active ingredient

Purified water USP

98.577% w/v

Purpose

Eyewash

Use

Use for flushing the eye to remove loose foreign material.

Warnings

For External Use Only

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

Do not reuse.

Once opened, discard.

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 nor, if twist-off Tamper Evident top is broken or missing.

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 at 36°-104°F

Use at 59°-86°F

Keep out of direct sunlight

Inactive ingredients

disodium EDTA
polyhexanide
sodium chloride
sodium hydroxide
sodium phosphate, dibasic
sodium phosphate, monobasic

Manufactured for:

Aero Healthcare

Congers, NY 10989

Made in Singapore

Package/Label Principal Display Panel

Drug Facts (contd.)

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Manufactured for:
AERO HEALTHCARE
Congers, NY 10989
Made in Singapore



REF AW1000US

STERILE A

NDC 55305-112-10
AW1000US V1



NO PRINT



EYEWASH

0.5 fl.oz. (15ml)

Drug Facts

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AEROWASH EYEWASH AND SKIN-RINSE

purified water solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55305-112
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WATER (UNII: 059QF0K00R) (WATER - UNII:059QF0K00R)	WATER	98.577 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
POLIHExANIDE (UNII: 322U039GMF)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM PHOSPHATE, DIBASIC, DODECAHYDRATE (UNII: E1W4N241FO)	
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55305-112-14	15 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product	06/01/2015	
2	NDC:55305-112-12	148 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2015	
3	NDC:55305-112-13	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2015	
4	NDC:55305-112-15	947 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/07/2018	

Drug Facts (contd.)

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AERO HEALTHCARE

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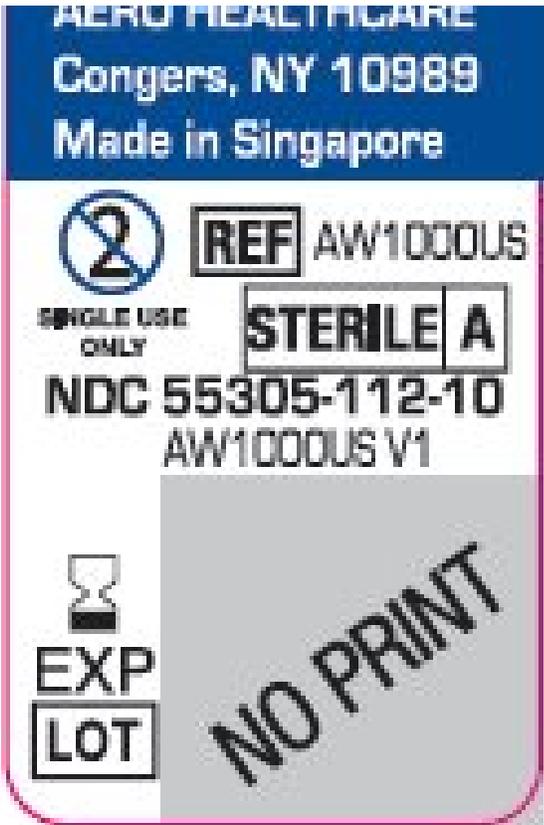
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	05/01/2015	

Labeler - Aero Healthcare (008186174)