

STERILE SALINE EYEWASH- water solution
Tongzhou Deqi Medical Products Factory

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.

Drug Fact

Active Ingredient

water 98.7%

Purpose

eyewash

Warnings

Do not use if solution changes color or becomes cloudy.remove contact lenses before use.stop use if eye pain continued redness or irritation of eye .

Keep out of reach of children.

Keep out of reach of children.in case of axcidental ingestion,seek professional assistance or consult a poison control center immediately.

Directions

Twist top to open,Flush eye as needed.

Use

for irrigating the eye to help relieve irritation by removeing loose foreign material.

Inactive Ingredients

Sodium chloride ,Potassium phosphate monobasic ,Sodium hydroxide,POLIHEXANIDE



STERILE SALINE
EYEWASH

NDC: 71222-006-01
15ml

Drug Facts:

Active ingredients:
Purified water 98.7%

Purpose: Eyewash

Uses: for irrigating the
eye to help relieve
irritation by removing
loose foreign material.

Storage: 59°F-86°F

Direction: Twist top to

open. Flush eye as needed.

Warnings:

Do not use if solution changes color or becomes cloudy. Remove contact lenses before use. Stop use if eye pain, continued redness or irritation of eye. Keep out of reach of children if swallowed get medical help or contact a Poison Control Center right away.

Inactive ingredients:
Polihexanide, potassium phosphate monobasic,

sodium chloride,
sodium hydroxide.

Tongzhou Deqi

Medical Products Factory

No.1, Qibei Village,

Tongzhou District,

Nantong, China

STERILE SALINE EYEWASH

water solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71222-006
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WATER (UNII: 059QF0K00R) (WATER - UNII:059QF0K00R)	WATER	0.987 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POLYHEXANIDE (UNII: 322U039GMF)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:71222-006-01	10 mL in 1 PACKAGE; Type 0: Not a Combination Product	05/24/2017	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part349	05/20/2014		

Labeler - Tongzhou Deqi Medical Products Factory (544464252)

Establishment			
Name	Address	ID/FEI	Business Operations
Tongzhou Deqi Medical Products Factory		544464252	manufacture(71222-006)

Revised: 6/2017

Tongzhou Deqi Medical Products Factory