

EYE WASH SALINE- water sodium chloride solution
Davemed Healthcare Co., Ltd.

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.

Eye Wash Saline

Purpose

Eye, wounds wash

Active ingredient

Purified water, sodium Chloride

Uses

For topical irrigation of eyes, burns and wounds

Warnings

Use only if Solution is clear and container is undamaged

Do not heat over 66°C (150 F). Store at a cool dry place

Discard any unused solution. Single use only

Keep out of reach of children.

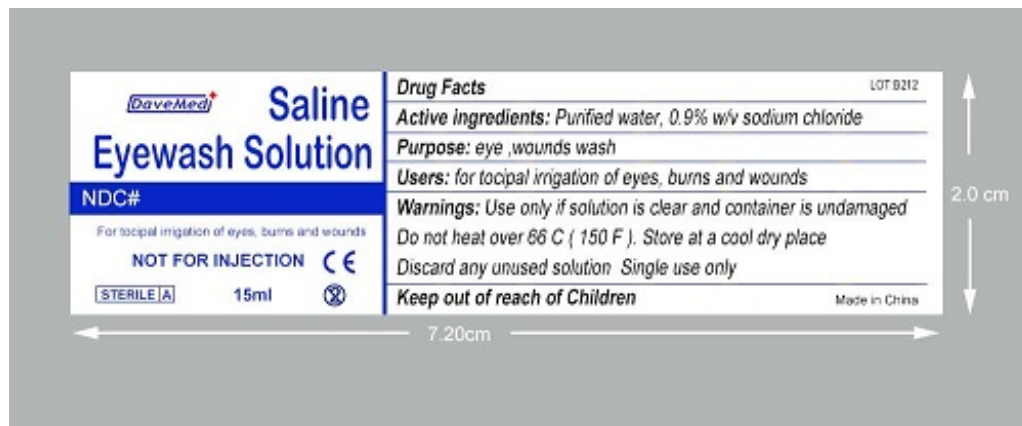
If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Not for injection

Inactive ingredients

boric acid, sodium borate, sodium chloride, Hydrochloric acid PRESERVATIVE ADDED: edetate disodium, polyhexamethylene biguanide



EYE WASH SALINE

water sodium chloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70897-002
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	0.9 mg in 100 mL
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	99.01 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SORBIC ACID (UNII: X045WJ989B)	
BORIC ACID (UNII: R57ZHV85D4)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70897-002-01	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/09/2016	
2	NDC:70897-002-02	20 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/09/2016	
3	NDC:70897-002-03	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/09/2016	
4	NDC:70897-002-04	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/09/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	08/09/2016	

Labeler - Davemed Healthcare Co., Ltd. (529128716)

Establishment

Name	Address	ID/FEI	Business Operations
Davemed Healthcare Co., Ltd		529128716	manufacture(70897-002)