SODIUM CHLORIDE- sodium chloride solution/ drops
Walgreens

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 Facts

Active ingredient

Sodium Chloride 5%

Purpose

Hypertonicity Agent

Use

For temporary relief of corneal edema

Warnings

Do not use

- this product except under the advice and supervision of a doctor
- if imprinted seal on bottle is missing or broken
- if solution changes color or becomes cloudy

When using this product

- temporary burning and irritation upon being instilled into eye may occur
- to avoid contamination, do not touch tip of container to any surface
- replace cap after each use

Stop use and ask a doctor if

- you experience eye pain
- you experience changes in vision
- redness or irritation of the eye continues
- condition worsens or persists

Keep out of reach of children.

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

Directions

Instill 1 or 2 drops in the affected eye(s) every 3 or 4 hours or as directed by a doctor.

Other information

- store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
- keep tightly closed.

Inactive ingredients

Boric Acid, Hydrochloric Acid*, Hypromellose 2906, Methylparaben 0.23 mg (0.023%), Propylene Glycol, Propylparaben 0.1 mg (0.01%), Purified Water USP, Sodium Borate, Sodium Hydroxide*. *May contain one or more of these ingredients to adjust pH (6.0 to 8.0).

Questions or Comments?

1-800-932-5676

Principal Display Panel Text for Container Label:

Well at

Walgreens NDC 0363-9040-00

STERILE

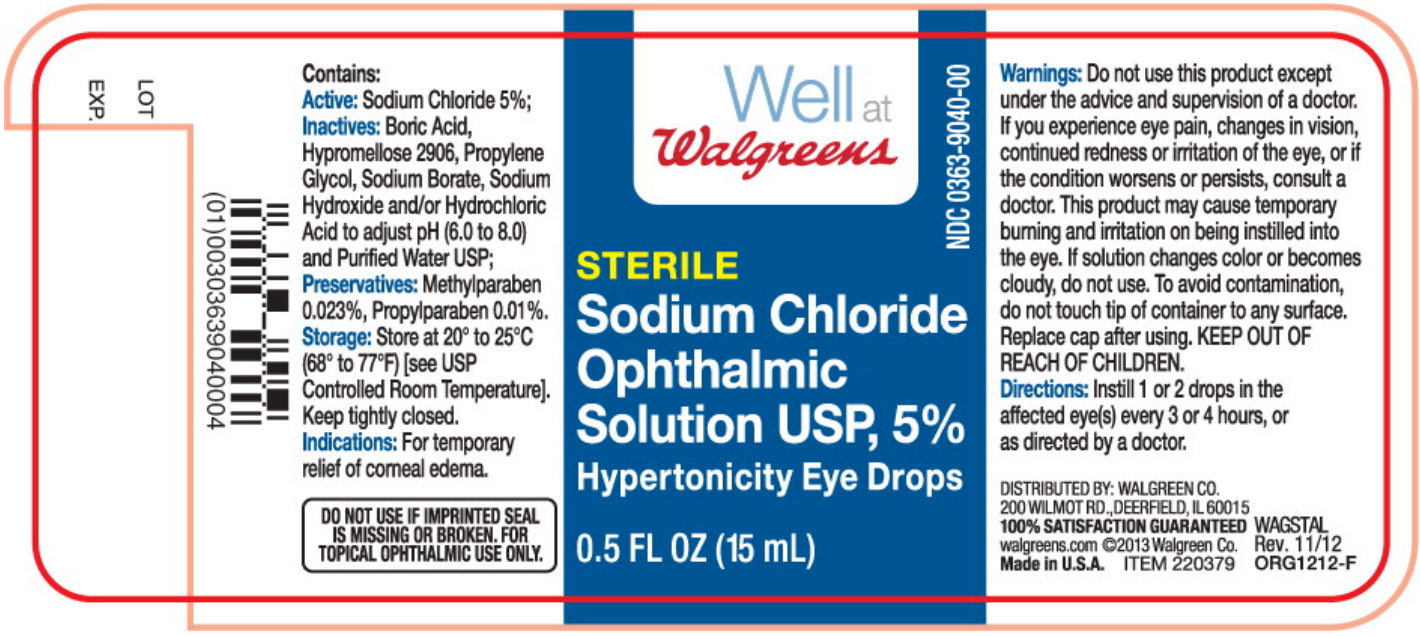
Sodium Chloride

Ophthalmic

Solution USP, 5%

Hypertonicity Eye Drops

0.5 FL OZ (15 mL)



Principal Display Panel Text for Carton Label:

Well at

Walgreens NDC 0363-9040-00

WALGREENS PHARMACIST RECOMMENDED≠

STERILE

Sodium Chloride

Ophthalmic

Solution USP, 5%

Hypertonicity Eye Drops

0.5 FL OZ (15 mL)

Compare to Muro 128®

active ingredient#

SODIUM CHLORIDE

sodium chloride solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0363-9040
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Chloride (UNII: 451W47IQ8X) (Sodium Cation - UNII:LYR4M0NH37)	Sodium Chloride	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Boric Acid (UNII: R57ZHV85D4)	
Hypromelloses (UNII: 3NXW29V3WO)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Sodium Borate (UNII: 91MBZ8H3QO)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Hydrochloric Acid (UNII: QTT17582CB)	
Water (UNII: 059QF0KO0R)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9040-00	1 in 1 CARTON		
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	02/12/2013	

Labeler - Walgreens (008965063)

Registrant - Akorn, Inc. (062649876)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn, Inc		063434679	PACK(0363-9040) , LABEL(0363-9040)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn, Inc.		155135783	MANUFACTURE(0363-9040) , ANALYSIS(0363-9040) , STERILIZE(0363-9040)