SODIUM CHLORODE HYPERTONICITY OPHTHALMIC SOLUTION- sodium chloride solution
Rugby Laboratories

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 ingredients

Sodium chloride 5%

Purpose

Hypertonicity agent

Uses

temporary relief of corneal edema

Warnings

Do not use

- except under the advice and supervision of a doctor
- if solution changes color or becomes cloudy

When using this product

- it may cause temporary burning and irritation
- to avoid contamination do not touch tip of container to any surface
- replace cap after use

Stop use and ask a doctor if

- condition worsens or persists for more than 72 hours
- you experience eye pain, changes in vision, continued redness or irritation of the eye

Keep out of reach of children.

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

Directions

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

Other information

- store upright at 15° - 25°C (59° - 77°F)
- keep tightly closed
- serious side effects associated with use of the product may be reported to the phone number provided below

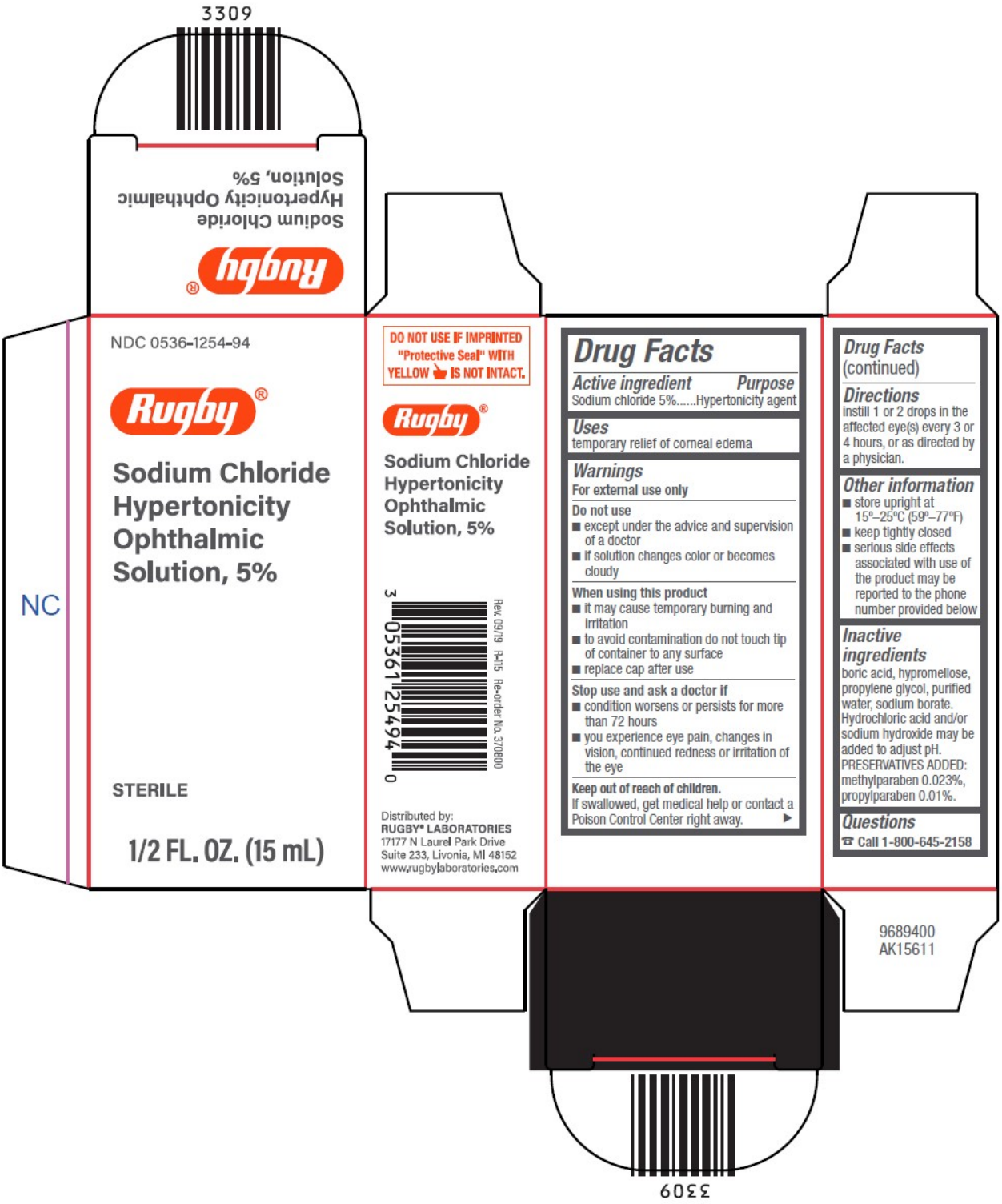
Inactive ingredients

boric acid, hypromellose, propylene glycol, purified water, sodium borate. Hydrochloric acid and/or sodium hydroxide may be added to adjust pH. PRESERVATIVES ADDED: methylparaben 0.023%, propylparaben 0.01%.

Questions?

[phone icon] **Call 1-800-645-2158**

Package/Label Principal Display Panel – carton



NDC 0536-1254-94

Rugby®

Sodium Chloride
Hypertonicity
Ophthalmic
Solution, 5%

STERILE

1/2 FL. OZ. (15 mL)

SODIUM CHLORODE HYPERTONICITY OPHTHALMIC SOLUTION

sodium chloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0536-1254
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)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0536-1254-94	1 in 1 CARTON	09/17/2020	
1		15 mL in 1 BOTTLE; 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	09/17/2020	

Labeler - Rugby Laboratories (079246066)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		079587625	MANUFACTURE(0536-1254)

Revised: 9/2020 Rugby Laboratories