SODIUM CHLORIDE HYPERTONICITY OPHTHALMIC- sodium chloride ointment
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 ingredient

Sodium chloride 50 mg (5%)

Purpose

Hypertonicity agent

Uses

temporary relief of corneal edema

Warnings

For external use only

Do not use except under the advice and supervision of a doctor

When using this product

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

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

- pull down the lower lid of the affected eye
- apply a small amount (1/4 inch) of ointment to the inside of eyelid
- apply every 3 or 4 hours or as directed by a doctor

Other information

- store at 15° - 25°C (59° - 77°F)
- keep tightly closed
- **DO NOT FREEZE**
- see crimp of tube or carton for Lot Number and Expiration Date
- do not use if difficult to dispense or visible particles are seen in the product
- serious side effects associated with use of the product may be reported to the phone number below

Inactive ingredients

lanolin, mineral oil, purified water, white petrolatum

Questions **[phone icon]**

Call 1-800-645-2158

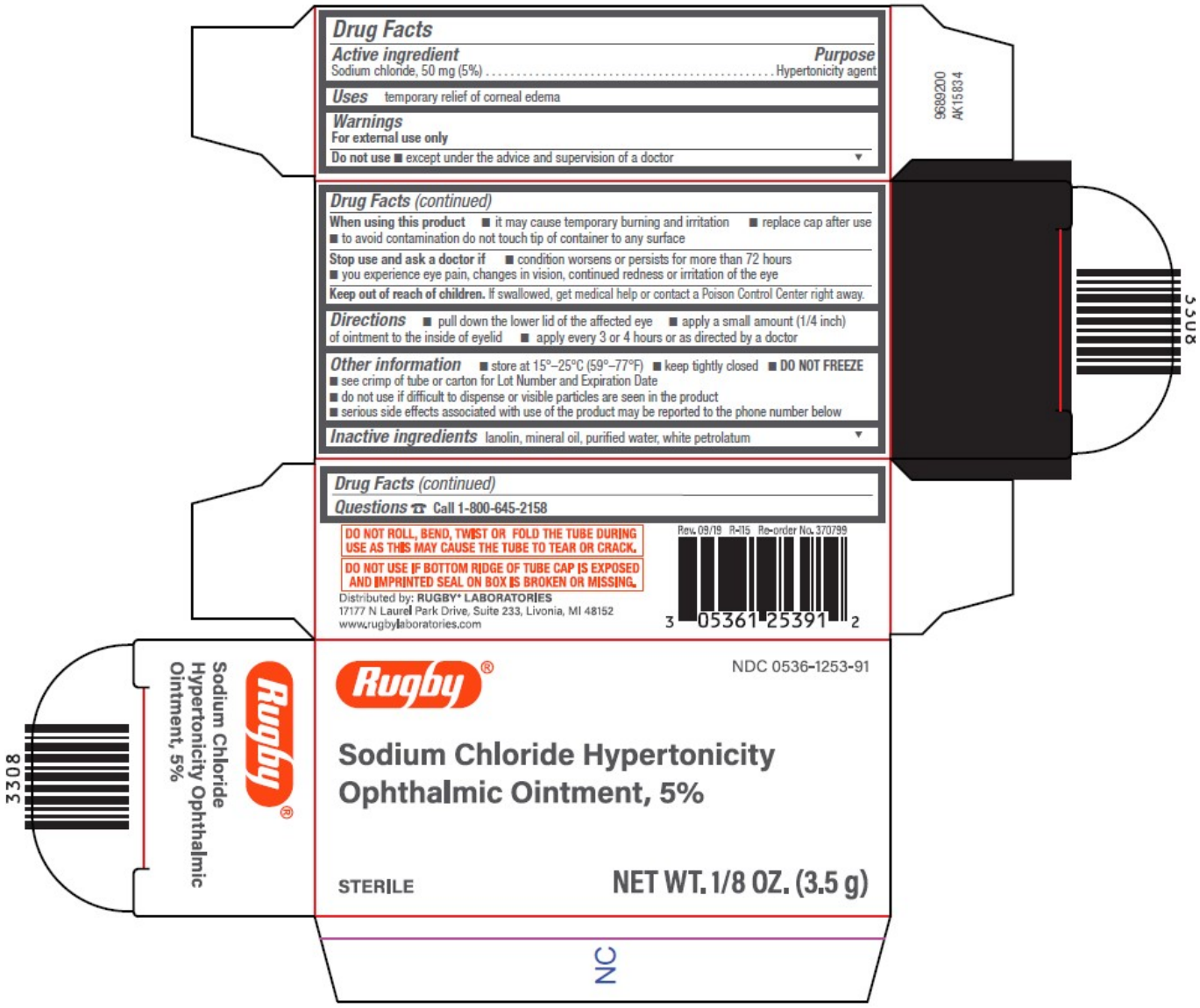
Package/Label Principal Display Panel Carton

Rugby®

NDC 0536-1253-91

Sodium Chloride Hypertonicity
Ophthalmic Ointment, 5%

STERILE NET WT. 1/8 OZ. (3.5 G)



SODIUM CHLORIDE HYPERTONICITY OPHTHALMIC

sodium chloride ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0536-1253
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 g

Inactive Ingredients	
Ingredient Name	**Strength**
LANOLIN (UNII: 7EV65EAW6H)	

MINERAL OIL (UNII: T5L8T28FGP)	
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1253-91	1 in 1 CARTON	11/06/2020	
1		3.5 g in 1 TUBE; 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	11/06/2020	

Labeler - Rugby Laboratories (079246066)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		079587625	MANUFACTURE(0536-1253)

Revised: 11/2021 Rugby Laboratories