SODIUM CHLORIDE- sodium chloride ointment
Akorn

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.**
- **Do not use if bottom ridge of tube cap is exposed**
- **To avoid contamination, do not touch tip of container to any surface.**
- **Replace cap after using.**
- **May cause temporary burning and irritation upon application into the eye.**

Stop use and ask a doctor if

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

Keep out of reach of children.

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

Directions

Apply small amount (one-fourth inch) to the inside of affected eye(s) every 3 to 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].**

- **Store away from heat.**
- **Protect from freezing.**
- **Keep tightly closed.**
- **See crimp for Control Number and Expiration Date.**
- **RETAIN THIS CARTON FOR FUTURE REFERENCE.**

Inactive ingredients

Mineral Oil, Modified Lanolin, Water for Injection and White Petrolatum.

Principal Display Panel Text for Container Label:

NDC 17478-622-35

Sodium Chloride Ophthalmic

Ointment USP, 5%

Hypertonicity Eye Ointment Sterile

FOR OPHTHALMIC USE ONLY. Net Wt. 3.5 g (1/8 oz.)

Principal Display Panel Text for Carton Label:

NDC 17478-622-35

3.5 g

Sodium

Chloride

Ophthalmic

Ointment

USP, 5%

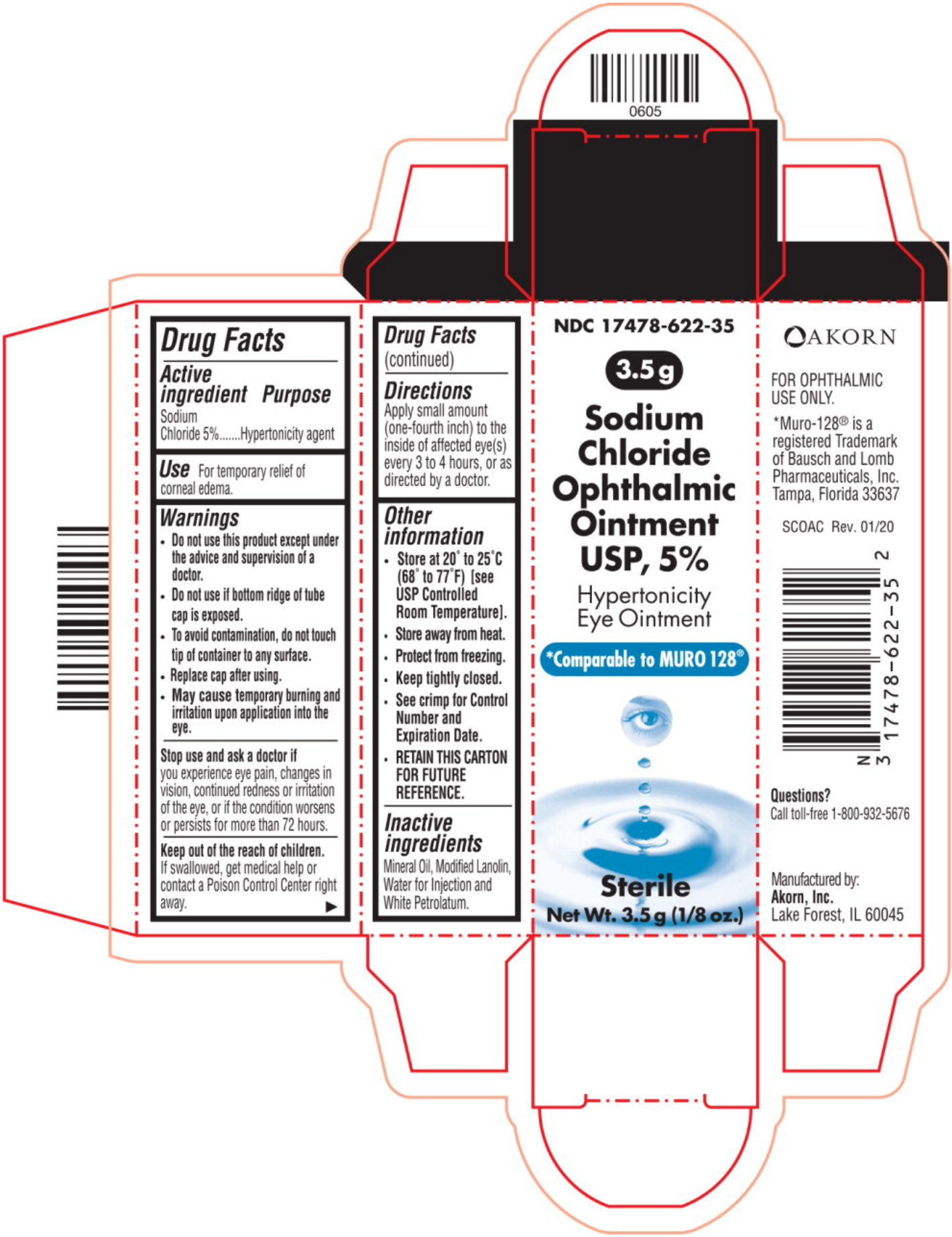
Hypertonicity

Eye Ointment

Comparable to MURO 128®

Sterile

Net Wt. 3.5 g (1/8 oz.)



SODIUM CHLORIDE

sodium chloride ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17478-622
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Sodium Chloride (UNII: 451W47IQ8X) (Sodium Cation - UNII:LYR4M0NH37, Chloride Ion - UNII:Q32ZN48698)	Sodium Chloride	50 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
Mineral Oil (UNII: T5L8T28FGP)	
Lanolin (UNII: 7EV65EAW6H)	
Water (UNII: 059QF0KO0R)	
Petrolatum (UNII: 4T6H12BN9U)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:17478-622-35	1 in 1 CARTON	05/08/2006	
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	05/08/2006	

Labeler - Akorn (117696770)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696840	MANUFACTURE(17478-622) , ANALYSIS(17478-622) , STERILIZE(17478-622) , PACK(17478-622) , LABEL(17478-622)