

SODIUM CHLORIDE- sodium chloride ointment

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
- do not use if cap skirt is dislodged from tube
- 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 occur
- continued redness or irritation of the eye
- 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 Lot Number and Expiration Date
- **Retain this carton for future reference**

Inactive ingredients

- Mineral Oil, Modified Lanolin, Purified Water and White Petrolatum.

Questions or comments?

1-800-932-5676

Principal Display Panel Text for Container Label:

STERILE Well at

Sodium Chloride Walgreens

Ophthalmic Ointment NDC 0363-9050-00

USP, 5% NET WT 3.5 g (1/8 oz.)

Hypertonicity Eye Ointment

FOR OPHTHALMIC USE ONLY

The image shows a rectangular label for a tube of ointment. The top section is a dark blue header with white text. On the left, it reads 'STERILE Sodium Chloride Ophthalmic Ointment USP, 5% Hypertonicity Eye Ointment FOR OPHTHALMIC USE ONLY'. On the right, it features the 'Well at Walgreens' logo and 'NET WT 3.5 g (1/8 oz.)'. A vertical NDC number 'NDC 0363-9050-00' is printed on the right edge. Below the header, the text is in a lighter blue background. It starts with 'READ OUTER CARTON FOR INFORMATION BEFORE USING.' followed by 'ACTIVE INGREDIENT: Sodium Chloride 5% (50 mg/g) INACTIVES: Mineral Oil, Modified Lanolin, Purified Water and White Petrolatum.' Then 'INDICATIONS: For temporary relief of corneal edema.' and '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. See crimp for Lot Number and Expiration Date.' Next is 'STORAGE: Store at 20° to 25° C (68° to 77°F) [see USP Controlled Room Temperature]. KEEP TIGHTLY CLOSED.' and 'KEEP OUT OF REACH OF CHILDREN.' A warning box contains 'DO NOT USE IF BOTTOM RIDGE OF TUBE CAP IS EXPOSED'. At the bottom left, it says 'DISTRIBUTED BY: WALGREEN CO. 200 WILMOT RD., DEERFIELD, IL 60015 100% SATISFACTION GUARANTEED walgreens.com ©2013 Walgreen Co.' In the center, it has 'ITEM 220378 ORG0113-F2' and a barcode with the number '(01) 00303639050003'. On the right side, there is a vertical label 'LT-1065 WAGKQAL Rev. 11/12' and a small blue rectangular mark.

Principal Display Panel Text for Carton Label:

STERILE Well at

Walgreens NDC 0363-9050-00

WALGREENS PHARMACIST RECOMMENDED≠

Sodium Chloride

Ophthalmic Ointment

USP, 5%

Hypertonicity Eye Ointment

Compare to Muro 128®

Ointment active ingredient#

NET WT 3.5 g (1/8 OZ)



SODIUM CHLORIDE

sodium chloride ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-9050
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		
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:0363-9050-00	1 in 1 CARTON		
1		3.5 g in 1 TUBE		
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		603980319	MANUFACTURE(0363-9050) , ANALYSIS(0363-9050) , STERILIZE(0363-9050) , PACK(0363-9050) , LABEL(0363-9050)

Revised: 2/2014

Walgreens