SODIUM CHLORIDE- sodium chloride ointment
Akorn, Inc.

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.

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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, Purified Water and White Petrolatum.
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.)

READ OUTER CARTON FOR INFORMATION BEFORE USING.
Active Ingredient: Sodium Chloride 5% (50 mg/g); Inactives: Mineral Oil, Modified Lanolin, Purified Water, White Petrolatum.
INDICATIONS: For the temporary relief of corneal edema.
DIRECTIONS: Apply small amount (approximately 1/4 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.
STORAGE: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. KEEP TIGHTLY CLOSED.
KEEP OUT OF REACH OF CHILDREN.

DO NOT USE IF BOTTOM RIDGE OF TUBE CAP IS EXPOSED.

Mfg by:
Akorn, Inc., Lake Forest, IL 60045

S COAL Rev. 09/08

(01) 00317478622352

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 (1/8oz.)
sodium chloride ointment

### Product Information

**Product Type**
- HUMAN OTC DRUG

**Route of Administration**
- OPTHALMIC

**Item Code (Source)**
- NDC:17478-622

### Active Ingredient/Active Moiety

<table>
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<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>Sodium Chloride (UNII: 451W47IQ8X) (Sodium Cation - UNII:LYR4M0NH37, Chloride Ion - UNII:Q32ZN48698)</td>
<td>Sodium Chloride</td>
<td>50 mg in 1 g</td>
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### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
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<tbody>
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<td>Mineral Oil (UNII: T5L8T28FGP)</td>
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<tr>
<td>Lanolin (UNII: 7EV65EAW6H)</td>
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<tr>
<td>Water (UNII: 059QF0KO0R)</td>
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<tr>
<td>Petrolatum (UNII: 4T6HI2BN9U)</td>
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### Packaging

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<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tr>
<td>1</td>
<td>NDC:17478-622-35</td>
<td>1 in 1 CARTON</td>
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<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>3.5 g in 1 TUBE</td>
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### Marketing Information

**Marketing Category**
- OTC monograph final

**Application Number or Monograph Citation**
- part349

**Marketing Start Date**
- 05/08/2006

**Marketing End Date**
- |

### Labeler
- Akorn, Inc. (062649876)

### Establishment

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<th>Name</th>
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<td>Akorn, Inc</td>
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<td>MANUFACTURE(17478-622), ANALYSIS(17478-622), STERILIZE(17478-622), PACK(17478-622), LABEL(17478-622)</td>
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Revised: 6/2012

Akorn, Inc.