

SODIUM CHLORIDE- sodium chloride ointment
CVS Pharmacy

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 the reach of children.

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

Questions or comments? 1-800-932-5676

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 controlled room temperature 20° to 25°C (68° to 77°F).
- 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.

Principal Display Panel Text for Container Label:

CVS Health™ Logo NDC 59779-303-01

Sodium Chloride USP, 5%

HYPERTONICITY OPHTHALMIC OINTMENT

NET WT 0.125 OZ (3.5 g) STERILE

The image shows the principal display panel text for a carton label. It features the CVS Health logo and NDC number 59779-303-01. The product name is Sodium Chloride, USP 5% Hypertonicity Ophthalmic Ointment, with a net weight of 0.125 oz (3.5 g) and is sterile. The label includes detailed instructions for use, storage, and a warning to keep out of reach of children. A crimp is visible on the right side of the label.

CVS Health™ NDC 59779-303-01

Sodium Chloride, USP 5%
HYPERTONICITY OPHTHALMIC OINTMENT

NET WT 0.125 OZ (3.5 g) STERILE

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.

Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895
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LT-1080-1

Principal Display Panel Text for Carton Label:

CVS Health™ Logo Compare to the active ingredient in Muro® 128*

Sodium Chloride, NDC 59779-303-01

USP, 5%

HYPERTONICITY OPHTHALMIC OINTMENT

Temporary relief of corneal edema

NET WT 0.125 OZ (3.5 g) STERILE



SODIUM CHLORIDE

sodium chloride ointment

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:59779-303 |
| 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:59779-303-01 | 1 in 1 CARTON | 02/21/2013 | |
| 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 | 02/21/2013 | |

Labeler - CVS Pharmacy (062312574)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------|---------|-----------|--|
| Akorn | | 117696840 | MANUFACTURE(59779-303) , ANALYSIS(59779-303) , STERILIZE(59779-303) , PACK(59779-303) , LABEL(59779-303) |