**SODIUM CHLORIDE- sodium chloride solution/ drops**
**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.*

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**Sodium Chloride Ophthalmic Solution, USP**

***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.
- if imprinted seal is broken or missing.
- if solution changes color or becomes cloudy.

**When using this product**

- temporary burning and irritation upon being instilled into eye may occur.
- to avoid contamination, do not touch tip of container to any surface
- replace cap after each use

**Stop use and ask a doctor if**

- you experience eye pain.
- you experience changes in vision.
- redness or irritation of the eye continues
- condition worsens or persists.

**Keep out of reach of children.**

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

**Directions**

Instill 1 or 2 drops in the affected eye(s) as needed.

## Other information

- Store at 20° to 25°C (68° to77°F) [see USP Controlled Room Temperature].
- Keep tightly closed.

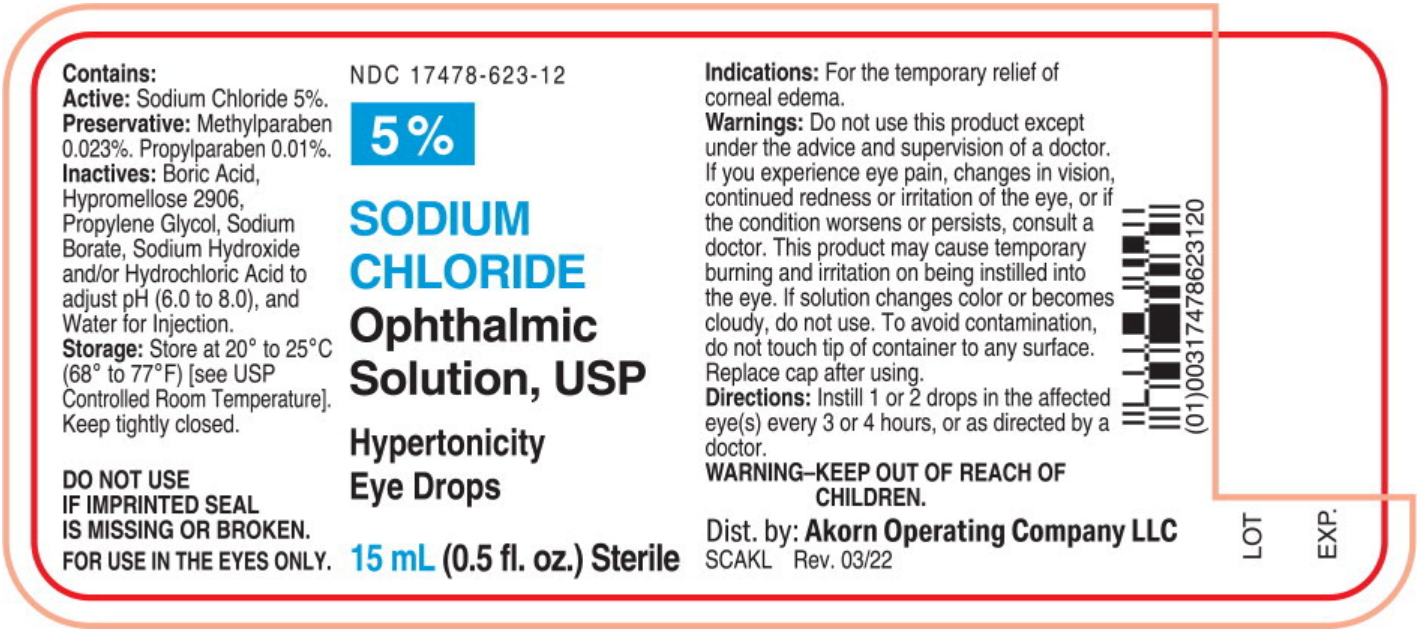
## Inactive ingredients

Boric Acid, Hypromellose 2906, Methylparaben 0.23 mg (0.023%), Propylparaben 0.1 mg (0.01%), Propylene Glycol, Sodium Borate, Sodium Hydroxide and/or Hydrochloric Acid to adjust pH (6.0 to 8.0), and Water for Injection.

Principal Display Panel Text for Container Label:

NDC 17478-623-12
5%
SODIUM
CHLORIDE
Ophthalmic
Solution, USP

Hypertonicity
Eye Drops
15 mL (0.5 fl. oz.) Sterile




Principal Display Panel Text for Carton Label:

NDC 17478-623-12
5%
SODIUM
CHLORIDE
Ophthalmic
Solution, USP

Hypertonicity Eye Drops

Comparable to Muro-128®*
15 mL (0.5 fl. oz.) Sterile

Akorn Logo


## SODIUM CHLORIDE

sodium chloride solution/ drops

### Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:17478-623 |
| **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 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **Boric Acid** (UNII: R57ZHV85D4) | |
| **Hypromelloses** (UNII: 3NXW29V3WO) | |
| **Propylene Glycol** (UNII: 6DC9Q167V3) | |
| **Sodium Borate** (UNII: 91MBZ8H3QO) | |
| **Sodium Hydroxide** (UNII: 55X04QC32I) | |
| **Hydrochloric Acid** (UNII: QTT17582CB) | |
| **Water** (UNII: 059QF0KO0R) | |
| **Methylparaben** (UNII: A2I8C7HI9T) | |
| **Propylparaben** (UNII: Z8IX2SC1OH) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:17478-623-12 | 1 in 1 CARTON | 04/01/1998 | |
| **1** | | 15 mL in 1 BOTTLE, DROPPER; 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 | 04/01/1998 | |

## Labeler - Akorn (117693100)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Akorn | | 117696790 | LABEL(17478-623) , PACK(17478-623) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Akorn | | 117696832 | MANUFACTURE(17478-623) , ANALYSIS(17478-623) , STERILIZE(17478-623) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Akorn | | 117696840 | ANALYSIS(17478-623) , LABEL(17478-623) , MANUFACTURE(17478-623) , PACK(17478-623) , STERILIZE(17478-623) |

Revised: 7/2022

Akorn