

SODIUM CHLORIDE- sodium chloride solution/ drops
Rite Aid Corporation

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.
- 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) every 3 or 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].
- 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 Purified Water USP.

Questions

call **1-800-579-8327**

Principal Display Panel Text for Container Label:

RITE
AID®
PHARMACY

eye care
ophthalmic
solution
sodium chloride USP 5%
hypertonicity
eye drops
Sterile
0.5 FL OZ (15 mL)

The image shows a simulated container label for Rite Aid eye care ophthalmic solution. The label is rectangular with rounded corners and a red border. It is divided into several sections. On the left, there are fields for 'EXP.' and 'LOT' with a barcode below them. The barcode has the number (01)00311822545816 printed vertically. The main body of the label is blue and white. At the top left is the Rite Aid Pharmacy logo. The product name 'eye care ophthalmic solution' is written in large, bold, black letters. Below that, 'sodium chloride USP 5%' is written in white on a blue background. Further down, 'hypertonicity eye drops' is written in white on a blue background. At the bottom left, 'Sterile 0.5 FL OZ (15 mL)' is written in white on a blue background. On the right side, there is a white background with black text for 'Indications', 'Warnings', 'Directions', and a 'WARNING-KEEP OUT OF REACH OF CHILDREN' notice. At the bottom right, it says 'DISTRIBUTED BY: RITE AID 30 HUNTER LANE, CAMP HILL, PA 17011 RTAKL Rev. 04/12'. At the bottom center, there is a warning: 'DO NOT USE IF IMPRINTED SEAL IS MISSING OR BROKEN. FOR USE IN THE EYES ONLY.'

EXP. **LOT**

(01)00311822545816

Contains:
Active: Sodium Chloride 5%.
Preservative: Methylparaben 0.023%. Propylparaben 0.01%.
Inactives: Boric Acid, Hypromellose 2906, Propylene Glycol, Sodium Borate, Sodium Hydroxide and/or Hydrochloric Acid to adjust pH (6.0 to 8.0), and Purified Water USP.
Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Keep tightly closed.

DO NOT USE IF IMPRINTED SEAL IS MISSING OR BROKEN. FOR USE IN THE EYES ONLY.

RITE AID PHARMACY

eye care ophthalmic solution

sodium chloride USP 5%

hypertonicity eye drops

Sterile 0.5 FL OZ (15 mL)

Indications: For the temporary relief of corneal edema.
Warnings: Do not use this product except under the advice and supervision of a doctor. If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists, consult a doctor. This product may cause temporary burning and irritation on being instilled into the eye. If solution changes color or becomes cloudy, do not use. To avoid contamination, do not touch tip of container to any surface. Replace cap after using.
Directions: Instill 1 or 2 drops in the affected eye(s) every 3 or 4 hours, or as directed by a doctor.
WARNING—KEEP OUT OF REACH OF CHILDREN.
DISTRIBUTED BY: RITE AID 30 HUNTER LANE, CAMP HILL, PA 17011 RTAKL Rev. 04/12

Principal Display Panel Text for Carton Label:

RITE
AID®
PHARMACY

Compare to the active
ingredient in Muro-128®*
NDC 11822-5458-1

eye care
ophthalmic
solution
sodium chloride USP 5%
hypertonicity
eye drops
temporary relief
of corneal edema
doctor recommended
Sterile
0.5 FL OZ (15 mL)



SODIUM CHLORIDE

sodium chloride solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-5458
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:11822-5458-1	1 in 1 CARTON	02/21/2013	
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	02/21/2013	

Labeler - Rite Aid Corporation (014578892)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696790	PACK(11822-5458) , LABEL(11822-5458)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696832	MANUFACTURE(11822-5458) , ANALYSIS(11822-5458) , STERILIZE(11822-5458)

Revised: 1/2022

Rite Aid Corporation