SODIUM CHLORIDE- sodium chloride solution/ drops HUB Pharmaceuticals

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.

Sodium Chloride 5% Solution USP (Sterile)

Drug Facts:

| Active Ingredient (each mL contains) | Purpose |
|--------------------------------------|---------------------|
| Sodium Chloride USP 5% w/v (50mg) | Hypertonicity agent |

Inactive Ingredients:

Boric Acid, Hypromellose, Propylene Glycol, Sodium Hydroxide and/or Hydrochloric Acid may be added to adjust pH, and Water for Injection.

Preservative:

| Methylparaben | USP 0.023% w/v |
|---------------|----------------|
| Propylparaben | USP 0.01% w/v |

Directions:

- To open, twist cap clockwise to puncture sterile seal.
- Remove cap.
- Instill 1 or 2 drops in the affected eye(s) every 3 or 4 hours as needed or directed by a doctor.

Dosage & Administration:

Instill 1 or 2 drops in the affected eye(s) every 3 or 4 hours as needed or directed by a doctor.

Indications:

For the temporaty relief of corneal edema.

For the temporaty relief of corneal edema.

External use only

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:

- temporoary burning and iritation upon being instilled into eye may occur
- To avoid contamination, do not touch top of container to any surface

• Replace cap after using, keep tightly closed

In case of accidental ingestion, seek professional help or contact a Poision Control Center immediately.

Stop use and ask a doctor if:

- you experience eye pain, changes in vision, continued redness, or irritation of the eye.
- if the condition worses or persists

save box for complete warnings and instructions

Keep out of reach of children

If swallowed, get medical help for contact a Poison Control Center immediately. Store at room temperature 15°-30°C (59°-86°F).

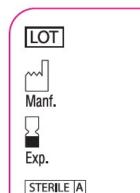
Questions?

1-800-Eye-Drop (393-3767) Monday to Friday 8 AM - 4 PM PST

REPRESENTATIVE PACKAGING:



Sodium Chloride Solution Label



Manufactured for:

HUB Pharmaceuticals, LLC Rancho Cucamonga, CA 91730

Rev. 10/2014 GUJ/DRUG/G-1197



Drug Facts

Active Ingredient: Sodium Chloride USP 5% w/v
Inactive Ingredients: Boric Acid, Hypromellose, Propylene
Glycol, Sodium Borate, Sodium Hydroxide and/or Hydrochloric
Acid may be added to adjust pH, and Water for Injection.

Preservative: Methylparaben USP 0.023%w/v, Propylparaben
USP 0.01% w/v

Directions: To open, twist cap clockwise to puncture sterile seal. Remove cap. Instill 1 or 2 drops in the affected eye(s) every 3 or 4 hours, or as directed by a doctor.

Indications: For the temporary relief of corneal edema.

Warnings: KEEP OUT OF REACH OF CHILDREN

See outer carton for complete details.

Sodium Chloride Solution Box

SODIUM CHLORIDE

sodium chloride solution/ drops

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:17238-625

Route of Administration OPHTHALMIC

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthSODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)SODIUM CHLORIDE50 mg in 1 mL

Inactive Ingredients Ingredient Name Strength METHYLPARABEN (UNII: A2I8C7HI9T) PROPYLPARABEN (UNII: Z8IX2SC10H) BORIC ACID (UNII: R57ZHV85D4) HYPROMELLOSES (UNII: 3NXW29V3WO) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) SODIUM BORATE (UNII: 91MBZ8H3QO) WATER (UNII: 059QF0KO0R) SODIUM HYDROXIDE (UNII: 55X04QC32I) HYDROCHLORIC ACID (UNII: QTT17582CB)

| 1 | Packaging | | | | |
|---|----------------------|-------------------------------|------------|-----------------------|--|
| # | Item Code | Item Code Package Description | | Marketing End Date | |
| 1 | NDC:17238-625- 15 | 1 in 1 BOX | 10/15/2014 | | |

| | omL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination roduct | | | |
|-----------------------|--|----------------------|--------------------|--|
| | | | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part349 | 09/12/2013 | | |
| | | | | |

Labeler - HUB Pharmaceuticals (611747945)

| Establishment | | | | | | |
|--|---------|-----------|------------------------|--|--|--|
| Name | Address | ID/FEI | Business Operations | | | |
| Conta Care Ophthalmics and Diagnostics | | 915821765 | manufacture(17238-625) | | | |

Revised: 12/2017 HUB Pharmaceuticals