NORMAL SALT- sodium chloride tablet GRAXCELL PHARMACEUTICAL, LLC

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 Tablets, USP; Normal Salt Tablets (1 gram), 70795-1120

Active ingredient (in each tablet)

Sodium Chloride, USP 1.0 gram

Purpose

Electrolyte Replenisher

Uses

- for the preparation of normal isotonic solution of Sodium chloride
- as an electrolyte replenisher for the prevention of heat cramps due to excessive perspiration
- any alternative use as directed by a physician

Warnings

Enter section text here

Do not use

without consulting a physician

Ask a physician before use

if you have a sodium restricted diet due to multiple organ diseases

Stop use and ask a physician

If symptoms of heat cramps continue for more than 24 hours

If pregnant or breast-feeding

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away

Directions

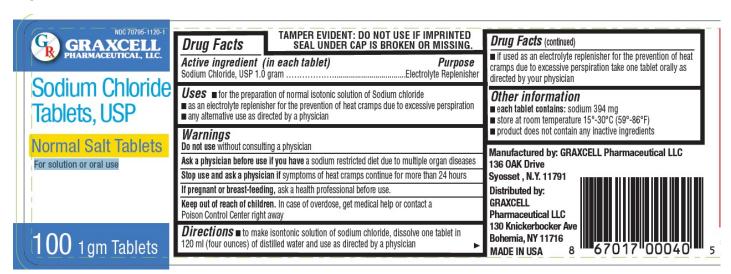
- to make isontonic solution of sodium chloride, dissolve one tablet in 120 ml (four ounces) of distilled water and use as directed by a physician
- if used as an electrolyte replenisher for the prevention of heat cramps due to excessive perspiration take one tablet orally as directed by your physician

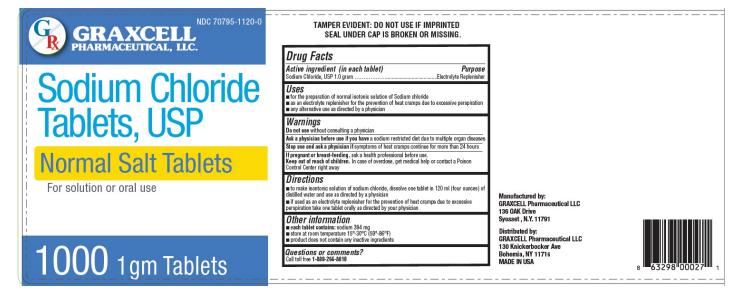
Other information

- each tablet contains: sodium 394 mg
- store at room temperature 15°-30°C (59°-86°F)
- product does not contain any inactive ingredients

INACTIVE INGREDIENTS

NONE







Sodium Chloride Tablets, USP

NORMAL SALT TABLETS For solution or oral use

Value Size

1 Gram (15.4 gr.) 300 TABLETS

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TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING.

Manufactured by: Graxce Pharmaceutical, LLC. 136 Oak Drive Syosset, NY 11791

Distributed by: Graxce Pharmaceutical, LLC. 130 Knickerbocker Ave, Suite J Bohemia, NY 11716



Lat No. Exp., Date

NORMAL SALT

sodium chloride tablet

Product Information

Product Type HUMAN OTC DRUG **Item Code (Source)** NDC:70795-1120

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698) SODIUM CHLORIDE 1 g

Inactive Ingredients

Ingredient Name Strength

POWDERED CELLULOSE (UNII: SMD1X3XO9M)

Product Characteristics

| Color | white | Score | no score |
|----------|-------|--------------|----------|
| Shape | ROUND | Size | 13mm |
| Flavor | | Imprint Code | G13 |
| Contains | | | |

Packaging

| | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-------------------------------|---|-------------------------|-----------------------|
| | 1 NDC:70795- 1120-1 | | | |
| П | NDC 70705 | 1000 in 1 DOTTLE Time O Net - Compline ties | | |

| | ирс:70795- 1120-0 | Product | 10/02/2017 | |
|---|----------------------|--|------------|--|
| | NDC:70795- 1120-3 | 300 in 1 BOTTLE; Type 0: Not a Combination Product | 11/16/2020 | |
| 4 | NDC:70795- 1120-4 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 11/16/2020 | |

| Marketing Information | | | | |
|---|---------|-------------------------|-----------------------|--|
| Marketing Application Number or Monograph Category Citation | | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part349 | 10/02/2017 | | |
| OTC monograph final | parts49 | 10/02/2017 | | |

Labeler - GRAXCELL PHARMACEUTICAL, LLC (056556923)

| Establishment | | | | |
|------------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| GRAXCELL PHARMACEUTICAL, LLC | | 056556923 | manufacture(70795-1120) | |

Revised: 12/2021 GRAXCELL PHARMACEUTICAL, LLC